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Original Article

The Challenge of International Sanctions Against Iranian Radio-pharmaceutical Industry

Tahereh Miremadi

Iranian Research Organization for Science and Technology (IROST)

Abstract

This paper is about Iranian health industry facing the challenges created by the comprehensive international sanctions. This paper aims to give a realistic account of the different positive and negative impacts of the factor of international collaboration (or rather, the lack thereof) on the dual aspects of "technological and non-technological" catching up process. The case study is radio-pharmaceutical industry in Iran during the international sanctions (2000-2013) and the aftermath. The theoretical foundation relies on a hybrid framework of technological innovation systems approach and global value chain analysis. Drawing on the first pillar, it evaluates the structural and functional analysis of the radiopharmaceutical innovation system which is now technologically self-reliant to meet the domestic needs. The study of global value chain as the second pillar, sets the backdrop to evaluate Iranian status for market-entry in the region. The paper concludes that the international sanctions have worked as inducers to reach to the technological catching – up while blocking it to entry into the regional market. The paper offers some suggestion for policy advice at the end. As the policy advice, the paper maintains that Iran is now poised, to stretch its market to neighboring countries and benefit from the geographical and relational proximity it has within the region. It proves to be not an easy task, however. To attain this objective, it needs to establish a costly infrastructure and update different laws and regulations like FD, intellectual property right and create the right atmosphere for entrepreneurship, a process of institutional catch-up which requires a separate study.

Keywords: Global Value Chain, Technological Innovation System, Iran, Radio pharmaceuticals, JCPOA, functional upgrading

****Corresponding author*:** Tahereh Miremadi (Ph.D), Iranian Research Organization for Science and Technology (IROST)
Tel: +989122977600
Email address: tamiremadi@yahoo.com

Introduction

While enumerating the commonalities of successful technological catching up, Malerba and Nelson address the access to foreign technology and international networking as the second most important factor only next to the learning and the formation of capabilities of domestic firms (Nelson 2011). In the absence of such important factor, the caching up process looks like learning without internationally interacting with the world. This shortcoming might sound jeopardizing the total process. Yet, the history proves the reality is more complex than this blunt conclusion. The reason was this pseudo isolation of Iranian industry in some sectors actually provide a favorable environment for technological and market niche development which otherwise were saturated by international brands. The experiences of technological capability building in some of the Iranian industries during the international sanctions 1996 -2012 have some valuable lessons for researchers who plan to study the role of international knowledge interactions (or rather, the lack thereof) in the process of technological catch-up. Among these sectors, the radiopharmaceutical innovation system is an example par excellence.

This paper aims to examine the points of strength and weakness of the nuclear medical technology capability building process in the post-revolution era in Iran and asks what the challenges and opportunities have been for this field during the sanction era. Drawing on a hybrid model rooted in the literature (Pietrobelli 2009) of Global Value Chain (Gereffi and al. 2005) and Innovation System (Anna Bergek 2009), (Hekkert 2007), it analyzes the global value chain of radiopharmaceuticals, its governance and learning patterns of its members as a landscape. Then, it studies the nuclear medical technological innovation system in Iran in terms of structural and functional aspect to have the strong and weak points of the technological development process. In the last part, the paper explains the potential leverage that Iran has gained during the years of isolations for joining the global value chain after nuclear taks. It also probes the risks this country might be running by exposing itself to the foreign competitors and international scrutiny in such strategically health oriented industry. The result will be elaborated in the shape of a SWOT analysis at the end.

Defining the technology in focus; Radiopharmaceuticals:

Nuclear technologies have the ability to fight against diseases, including cancer which is a growing global health problem. The application of radiation and radioisotopes in medicine particularly for diagnosis and therapy of various medical conditions are also very important. In most developed countries about one person in fifty uses diagnostic nuclear medicine each year. Over 10,000 hospitals worldwide use radioisotopes in medicine and the use of radiopharmaceuticals in diagnosis is growing at over 10% per year (World Nuclear Association 2015). In Iran, there are more than 160 center of nuclear medicine placing Iran at the top of all countries in the region (D. B. Amir Reza Jalilian 2016).

Easy availability of radiopharmaceuticals is a key element in the application of radioisotopes in health care. This prospect is enhanced by on-demand availability of the pharmaceuticals through reliable imports and creating some degree of self-sufficiency within the country and the geographical region.

The easy and reliable availability of Mo-99 and Tc-99 is the key element for application of radioisotopes in health care. However, access to these products through the international market does not look practical for many developing countries, since neither domestically producing radiopharmaceuticals nor relying on the import is a risk free strategy for them.

Many hassles arise from international regulations or difficult logistics of importation from a manufacturing site to the point of use. As a result, compromised patient care system can become a real issue for those societies lacking indigenous manufacturing capabilities, and those which have to depend upon unreliable sources for these products.

The barrier for creating technological capability often cited is that of cost for countries like Bangladesh or the shortage of trained human resources and the lack of knowhow for Saudis Arabia) (World Nuclear Association 2015).

For Iran, however, the barrier has been the lack of capital or manpower, but the limited access

this country has had to the international technology networks and global value chain due to the international export control regime.
In retrospect, this challenge has provided this country with an excellent opportunity to build an indigenous radiopharmaceutical innovation technology. It has paved the way for Iran to provide its citizens the nuclear medicine service in an accelerating rate of growth since 1980s.
Iran has worked to gain command in production of radiopharmaceuticals to meet its domestic needs. It has been self reliant on Tc-99 generators, the most important radio-medicine, for several years. (Iran Assciation of Nuclear Medicine 2015). These attempts made Iran a leading country in the region, despite the unfavorable international export regime hitting its economy and blocking its interactions with the world leaders of nuclear medical technology (D. B. Amir Reza Jalilian 2016).

The Conceptual Model; a hybrid Framework of IS and GVC

The paper's foundation lays down on the double conceptions of Keun Lee and Chaisung Lim (Lim 2001) differentiating between technological catching-up and market catching up. To study these two types of catching up, the paper built a hybrid framework based on two theoretical paradigms of Global Value Chain Analysis (GVC) (Gereffi and al. 2005) and Innovation System (IS) (Anna Bergek 2009).
GVC is a line of analysis describing the full range of activities that firms do to develop a commodity from a concept to final product at the global level. The focus of the GVC research is on the linkages through which information and knowledge, as well as goods, flow among the various actors involved in the chain and on their implications for development. The concept of governance is crucial to the analysis of the relationships among actors in the chain that might, in turn, facilitate or hinder the transfer of knowledge between the different actors (Gereffi and al. 2005).
The GVC analysis suffers from a significant shortcoming because it does not pay much attention to the institutional context within which local firms interacting in GVCs are embedded. At this point, innovation system (IS) approach can complement the analysis of GVC. It serves as a platform to study those elements and relationships which interact in the production, diffusion and use and application of new and economically useful knowledge either located within or rooted inside the borders of a nation state (lundvall 2009).
While relying on the hybrid model of IS and GVC already introduced by the scholars (Pietrobelli 2009), the paper deviates from them to employ the functional approach of sectoral innovational system with seventh functions. The F7 , legitimization has a double role ; one is internal advocacy to develop this technology domestically. The second is the benefitting from international approval and standards to entry to the regional market .
The data was gathered by visiting the R&D and production sites, interviews with the Iranian and international experts (EU delegations during their visit Tehran)[1] , reviewing the official and companies' marketing documents and the reports of the international organizations and foreign watchdogs monitoring the Iranian

1. The visit was coordinated under the umbrella of EU 2525 . The interview was conducted in March 2016.

Fig.1: the double conception of catching up

nuclear technology. At the end, SWOT Matrix was employed to analyze the discussions and to articulate the research findings.

Global Value Chain of Radiopharmaceuticals and the Mixed Governance Package:

Radioisotopes and radiation are essential parts of the medical diagnostic procedures and have many applications in medicine and medical research. Over 10,000 hospitals worldwide use radioisotopes in medicine, and about 90% of the procedures are for diagnosis. In developed countries (26% of world population), the frequency of diagnostic and therapy is 1.9% and 0.19%, respectively. The use of radiopharmaceuticals is growing at over 10% per year. (World Nuclear Association 2015).

As commodities, radioisotopes have some characteristics which complicate any nation's process of decision making on whether to import or produce it: First, it has a short shelf-life. Physical half-life determines whether a radioisotope must be produced locally or whether it can be imported from another region of the country or from a foreign country (Fisher 2008). Moreover, the relatively short physical half-lives [2] of radioisotopes determine the most desirable physical properties for specific applications and increase the daily or weekly supply challenge (Fisher 2008).

Furthermore, the industry has some specific international security concerns since any available radioactive material, in the hands of wrong people, could be used as radiological dispersive weapons. Therefore, the knowledge networks and the supply chains are the subjects of international scrutiny and export control regimes.

The most common radioisotope used in diagnosis is technetium-99 or Tc-99. Tc-99, in medical imaging techniques, accounts for over 80 % of all nuclear medicine procedures, representing over 30 million worldwide. Alternatives to Tc-99 are very costly and may result in a higher dose rate to the patient (James Welsh 2015).

In the global value chain of this technetium-99, the decay product of Molybdenum 99 (Mo-99), there are four significant links:

2. The period in which the radioactivity or number of atoms of a radioactive substance decreases by half; similarly applied to any substance, such as a drug in serum,whose quantity decreases exponentially with time.

1. The First Link: There are two primary processes for producing molybdenum-99 (Mo-99): fission of uranium-235 (U-235) and neutron capture of molybdenum-98 (Mo-98). Over 95% of the 99Mo required for 99mTc generators is produced by the fission of uranium-235 targets (PONSARD 2010). There are only five nuclear reactors involved in this production on industrial scale (PONSARD 2010), (Seeverens 2015).

2. - The Second Link: Isotope production facilities process the HEU targets to extract and purify Mo-99. An irradiation time takes about 168 hours and needs a cooling period of 12 hours. Then, the irradiated targets are loaded into shipment containers and sent to four processing facilities supplying about 95% of the 99Mo global needs.

3. - The Third Link: The bulk 99Mo is sent to other companies for the manufacture of the 99Mo/99mTc generators.

4. - Finally, the 99Mo/99mTc generators are supplied to hospitals or central pharmacies as shown in Fig. 2 and can normally be used for only 1 week because of the loss of 1% of activity per hour. (PONSARD 2010), (Seeverens 2015).

Figure 2: Mo-99 supply chain
Source: (Seeverens 2015)

The global radioisotope market was valued at $4.8 billion in 2012, with medical radioisotopes accounting for about 80% of this, and is poised to reach about $8 billion by 2017. North America is the dominant market for diagnostic radioisotopes with close to half of the market share, while Europe accounts for about 20%. (World Nuclear Association 2015)

The industry is highly concentrated. Eight reactors are now active in the first link, providing the bulk of irradiation services to meet the global estimated demand of about 10,000 six-day curies per week. In order of capacity, they are Belgium's BR2, the Dutch HFR, the Canadian NRU, the South African SAFARI, the Czech LVR-15, the Polish MARIA, the French OSIRIS, and the Australian OPAL. In

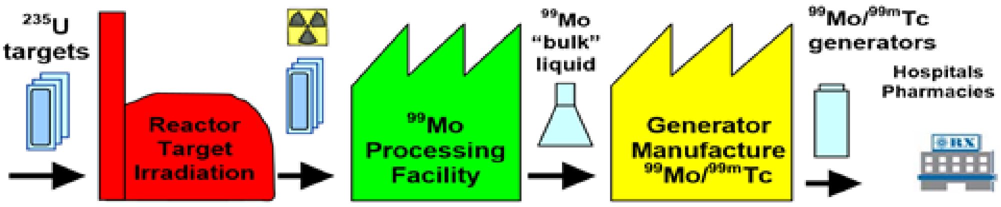


Figure 2: Mo-99 supply chain

Source: (*Seeverens* 2015)

the second link, the processor market is more concentrated with five firms capable of processing 1000 or more six-day curies per week. In order of capacity, they are Nordion (Canada), Mallinckrodt (Netherlands), NTP (South Africa), IRE (Belgium), ANSTO (Australia). The Tc-99m generator market, in the third link, is dominated only by two firms: Mallinckrodt, with operations in the Netherlands, and U.S-based Lantheus Medical Imaging who together control more than 80% of the global Tc-99m generator market.

Taking into account the utilization ratio of the installed Mo-99 production capacity, as well as production at smaller facilities, this is what the breakdown of global production by country/region looks like:

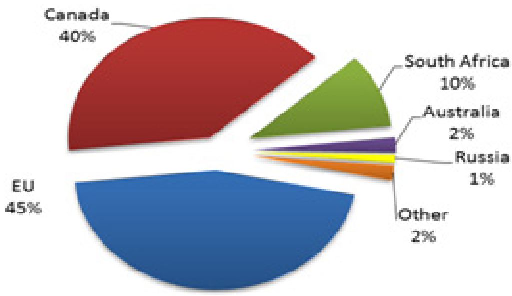
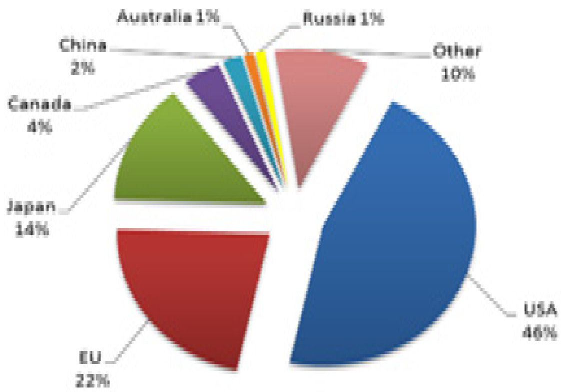


Figure: 3: Global production share (Valeriya Chekina 2014)

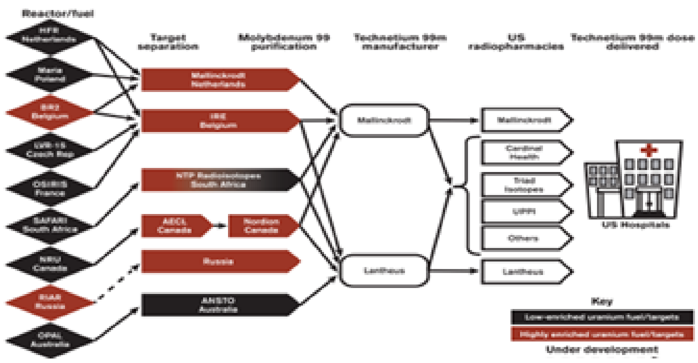
Each player has a specific role in the international supply chain of radio-pharmaceuticals. As you can see in Fig.2, the EU and Canada are the MO-99 producers with the most volume of production with 45 and 40 percent of the global market, respectively, while Russia with 1 percent is the producer with the least quantity. The US does not have any place in the first and second links of the value chain while this country is one of the main providers of HEU to the facilities in the first link and one of the two main players in providing the final product in the last links (final products) of supply chain. Consequently, US control the original input and the final output links of the global value chain and lead the GVC without having any American company in the three first links. The Europe and Canada share the leadership since they are dominant in the middle links of the value chain. The Russia and some other mostly developing countries (Indonesia, Egypt, Pakistan are the regional players each from 1% and less (IAEA 2010). Finally, the health facilities of the other countries are the users of Tc-99 generators, the last links of the global value chain.

This highly coordinated global value chain allows the availability of 99mTc every day, 365 days per year, on the basis of a weekly delivery of generators all around the world. Each partner in the supply chain must thus work very efficiently to avoid losing time so that the product can be delivered as quickly as possible for critical use of diagnosis and treatment worldwide.



Figoure.4: Breakdown of Global Mo-99 Demand by Country/Region

The governance of the radiopharmaceutical products is unique in two aspects:
First, due to the security and economic aspects, the governance of GVC of radioisotopes shapes an asymmetrical geometry laced with non-economic concerns. Comparing the figure 3 and 4, it shows that USA is the biggest market of Mo-99 while does not produce any. In fact, USA leadership of GVC is exerted by controlling the process of enrichment of uranium (by URENCO and USEC which both have 46 % of market share in total. (URENCO 2013)
). The other leverage of US is its huge market which forms also 46 percent of global demand pivoting around Lantheus and Mallinckdrot corporations.



Figoure 5: the global matrix of suppliers of the US market (Sher May 2014)

Profiting from organizational and relational proximity, Canada and EU with strong public institutions and interests entered in the production Mo-99 and leads these parts of value chain. Oppositely, the relations between the leading and other non-western countries with different security concepts like Russia and China are not the same. Due to their different shares and roles in the global value chain of radioisotopes, they do not have equal footings. Accordingly, the global governance is based on the mixed package of market and modular and relational bases among the leaders of GVC and mostly hierarchical and captive between the GVC leaders and the rest of the producers and users. The players do not have the same standard of product, process and competency. Concurrently, the policy instruments are more diversified. While the dominance of the leaders over suppliers and users of GVC exerts by inter or intra firms relations, in the Radiopharmaceuticals, the States and the international organizations mainly IEA and WHO play major roles. The instruments of the international organizations are monitoring, surveillance and inspecting. The second instrument is the establishment of different export

Table 1: the nuclear power reactors (IAEA 2016)

COUNTRY	Reactors in Operation		Reactors under Construction		Nuclear Electricity Supplied in 2015		Total Operating Experience through 2015	
	No of Units	Total MW(e)	No of Units	Total MW(e)	TW·h	% of Total	Years	Months
ARGENTINA	3	1 632	1	25	6.5	4.8	76	2
ARMENIA	1	375			2.6	34.5	41	8
BELARUS			2	2 218				
BELGIUM	7	5 913			24.8	37.5	275	7
BRAZIL	2	1 884	1	1 245	13.9	2.8	49	3
BULGARIA	2	1 926			14.7	31.3	159	3
CANADA	19	13 524			95.6	16.6	693	6
CHINA	31	26 774	24	24 128	161.2	3.0	209	2
CZECH REPUBLIC	6	3 930			25.3	32.5	146	10
FINLAND	4	2 752	1	1 600	22.3	33.7	147	4
FRANCE	58	63 130	1	1 630	419.0	76.3	2 048	4
GERMANY	8	10 799			86.8	14.1	816	7
HUNGARY	4	1 889			15.0	52.7	122	2
INDIA	21	5 308	6	3 907	34.6	3.5	439	6
IRAN, ISLAMIC REPUBLIC OF	1	915			3.2	1.3	4	4
JAPAN	43	40 290	2	2 650	4.3	0.5	1 739	0
KOREA, REPUBLIC OF	24	21 733	4	5 420	157.2	31.7	474	0
MEXICO	2	1 440			11.2	6.8	47	11
NETHERLANDS	1	482			3.9	3.7	71	0

control measures by the States on the import, use and possess of the enriched uranium and many radioisotopes like Mo-99 and Tech-99. The product and process codification, the standards, testing and quality control of process and products are among the policy instruments that this multifaceted international regime employs to structure the learning process patterns.

Nowadays, any country plans to entry the market of radio-pharmaceuticals has to have built confidence with market and non-market players.

However, as the result of recent technological innovations, GVC in the pharmaceuticals sounds to be changing rapidly. Technological forecasting suggests that the twenty first century is the age of LEU and non-reactor based technologies for producing Mo-99 and good manufacturing practice will be highly demanded. With lowering the importance of security concerns, the economic preferences are becoming more demanding. The relational and organizational proximity is expected to wither away. In this new picture, the governance and the related policy instruments and consequently, the learning pattern of the members in the GVC will change, consequently.

Technological Catching up under Pressure; a short history of radio pharmaceuticals Industry:

The Iranian nuclear program began in the late 1950s with the full support of US. In 1957, a nuclear cooperation agreement was concluded under the Atoms for Peace Program, followed by an agreement in 1960 to purchase a small, 5 MW pool-type research reactor and a Molybdenum, Iodine and Xenon Radioisotope production facility (MIX) (World Nuclear Association 2015). In 1967, Tehran's research reactor was fueled with highly enriched uranium (HEU) provided by the United States. The research reactor had been set first for educational and research purposes (Miremadi 2015). Concurrently, the Institute of Nuclear sciences and the Tehran Nuclear Research Center were established in Tehran University (Miremadi, 2015) (Shahverdi 2014). The Institute became a training center for the Iranian students in the nuclear science and technology as well as those from Iran's neighboring countries (Entessar 2009).

Later in 1972, the Atomic Energy Organization of Iran (AEOI) was founded to design and execute policies for nuclear technology development at the national level. At the same year, the University of Tehran and Shiraz admitted students in the field of nuclear technology. Furthermore, some were sent abroad by the government to study nuclear energy technology. In 1975, the Massachusetts Institute of Technology signed a contract with the AEOI for providing training for the first cadre of Iranian nuclear engineers (Miremadi 2015).Apart from working with the Americans, Iran signed several contracts with Germany and France to guarantee its position in the global value chain of nuclear energy in the seventies.

Nuclear medicine was introduced into the Iranian medical community in 1960, when Professor

Sadegh NezamMafi and his colleagues began their studies in nuclear endocrinology (particularly thyroid function evaluation) with an early-generation thyroid probe and a rectilinear scanner. (Gholamrezanezhad A 2010) The first g camera was installed at the Tehran University Center for Endocrinology and Nuclear Medicine in 1964.

This landscape of capacity building via international cooperation dramatically changed in the eighties. Following the Islamic Revolution, the young State faced the different export control regimes and various sanctions. It, consequently, sought to build the S&T infrastructure within the country and tried to develop the self-reliant industries which some of them were knowledge intensive (Sepehr Ghazinoory 2009) and (Tahereh Miremadi 2012).

Concerning nuclear technology, following certain unsuccessful efforts to acquire the parts, instruments, materials and products from the West, Iran switched to the countries which were not the main players in the nuclear medicine GVC like Russia, China and Pakistan, for receiving know-how, spare parts as well as human capital and the training.

However, it was the local scientific and industrial community who were trained before revolution who was the main contributor to build a self reliant technological system of radio isotopes during the following twenty years. Iranian industry of radiopharmaceuticals, nowadays, produces medical radio isotopes for the market with one million clinical applications. (D. B. Amir Reza Jalilian 2016). The rate of growth of this market is more than 2 times the global rate (23% versus 10%). It supplies more than 45 products in the form of diagnostic products (cold kits and radionuclide generators), therapeutic products and radio-chemicals (Pars Isotope Company 2015), (Nuclear Medicine Association Conference 2015).

It is now, poised to stretch its borders to encompass regional markets e.g. Pakistan, Afghanistan and Iraq.

The industry is based on an innovation system run with non-market goal oriented dynamism. The national S&T policy of radiopharmaceuticals was designed with the strategic priority from the outset. The goal was to avoid the international export control depriving the society of health security with full benefit of nuclear medicine. In retrospect, the international pressure has served Iranian radiopharmaceutical technology in different forms, it galvanized the human and financial resources, it created a favorable atmosphere full of expectations and prioritized it in the national policy agenda. Consequently, the challenges and threats have yielded positive effects in terms of national capacity building and opportunities with three defining moments in the evolution of the national three linked supply chains:

1- The first challenge was the procurement of fuel for the TRR. The TRR was designed at first to use highly enriched uranium fuel (near 99%). In 1988, while running dangerously low of the fuel delivered by US, Iran succeeded to receive supply from Argentina's National Atomic Energy Commission following the conversion of the TRR to use low-enriched uranium fuel (19.75%) (UN 1988). But in 2007, the prospect of crisis of the procurement of the fuel once again was looming large due to the fact that even LEU could not be imported according to the new international export control regime. This challenge was incrementally mounting since the TRR had to be scheduled for full time workload. Being refused to access to the fuel through global market, Iran embarked on its plan to enrich uranium to 20 percent in Natanz and then in Fordow sites and converted a significant portion of the enriched uranium to fuel plates for TRR, amid the deepening and widening of the international sanctions.[3]

2- The second challenge was the access to Molybdenum-99 due to the international sanctions in 2007. The Tehran Research Reactor (TRR), and complementary facilities for handling radioisotopes, is and has been the only reactor for producing radioisotope in Iran. At that time, TRR, a US built facility, had been working only

3. In January 2012, in a Design Information Questionnaire (DIQ), Iran informed the International Atomic Energy Agency (IAEA) that the FFEP's purpose is the production of UF6 enriched both to 5% U-235 for power reactors and 20% U-235 for research reactors. In 2011, Iran began installing entrifuges in one of the units, commencing enrichment in December of that same year. As of November 2013, Iran had produced approximately 221.4kg of UF6 enriched up to 20% U-235 at FFEP

a few hours a week for educational purposes. With the international sanctions[4] over nuclear technology, the role of TRR became indispensible in providing Molybdenum-99. Since the method of fission of U-235 was not fit for Iranian capacity level at that time, the method of neutron capture by Mo-98, was chosen despite its obvious weaknesses. The production of Molybdenum 99 lasted until Iran was able to import it from Russia from 2011.

3- The access to fuel has not been the only TRR problem; the research reactor is aging and reaching its safety limits. Moreover, by Tehran metropolitan area stretching to the West, the location of the reactor is surrounded by urban area, thus failing to live up to the safety and security standards. In the mid-1980's, Iran concluded that "the only alternative was a heavy water reactor which could use domestically produced UO2 and zirconium" and located away from population centers, in the "Khondab area near Arak". The project of the Arak heavy water was, then, designed to extend the domestic supply chain.

Consequently, the export control regime has, unintentionally, forced Iran to build several elements of an integrated supply chain starting with TRR producing Mo-99 by Mo98 neutron activation shipping to Pars Isotope Mo-99 processing facility for producing Tc-99 generators and the other production. The local supply chain ends with different productions delivered to nuclear medical centers. As mentioned before, since 2011, technetium-99 generators have been produced in Iran and meet the national demand in 160 nuclear medical centers. Other than Tc-99, Iran has built a separation facility for handling radioisotopes with the intention of synthesizing up to 20 different radioisotopes. (IAEA/215 n.d.).
The distribution of nuclear medical centers in 31 province of Iran can be seen in the below:

4. 2006 SC resolution

Figure 6: The distribution of nuclear medicine centers nationwide (D. B. Amir Reza Jalilian 2016)

The Structural Components and functional dynamics of Radio-Isotope innovation system:

In this part, based on functional approach of sectoral innovation system approach (Anna Bergek 2009), the structure and functions of radiopharmaceutical innovation is evaluated and its inducements and blocking mechanisms will be introduced.

Structure of Radio Pharmaceutical Innovation System:

Due to the security aspect of nuclear technology, the structural map of radio-pharmaceutical sector in the upper part of the value chain; the research and development and production ,is concentrated in the hands of a few players while the lower parts regarding the application are crowded with the private practitioners. The present mapping of radio-pharmaceutical innovation system has an integrated structure with 4 types of major players in which:

1-The AEOI (Atomic Energy Organization of Iran) is the main organization in charge of policy design and governance and goal setting. IAEA monitors its activities. The main actors in the research and development, including the TRR and radioisotopes productions are under its watch. These actors are:

1-1- Research Institute of Nuclear Science and Technology with its specialized departments in the agricultural and medical application of nuclear technology located in Karaj in 1991. A 30 Mega-electron volt (MeV) cyclotron accelerator supplied by Belgium's Ion Beam Applications, and a small Chinese-supplied and -installed cauldron are located there. (World Nuclear Association 2015)

1-2- Pars Isotope Company is a semi private company of which its director is designated by AEO. It is the main producer of radiopharmaceuticals in the country. It also provides services in calibration and irradiation to the Secondary Standard Dosimetry Laboratory (SSDL0. It is responsible to fulfill such duties as calibration of radiotherapy ionization chambers in Co-60 gamma ray field, calibration of ionization chambers in 60-300 kV X-ray field, and standard irradiation of samples at all Co-60 gamma ray dose levels, Standard irradiation of samples in 60-300 kV X-ray fields (Pars Isotpes 2015).

1-3-The AEOI is also responsible for the establishment of regulations for nuclear and radiation safety (under the 1989 act), licensing facilities, and supervision. To do these tasks, it established the Iran Nuclear Regulatory Authority (INRA) for regulation and safety, as well as monitoring, legal compliance and radioactive waste management.

2- There are some research universities e.g. Shariff Industrial University, Amir Kabir University of technology and Shahid Beheshti University which provide academic education for nuclear technology at the doctorate level. Shiraz University, Isfahan University, Azad University admit students at the B.S. level. Azad University has offered students the major of radio medicine.. Other than academic education, there are other centers for job training and educational services; the department of medicine of the Institute of Agricultural Research, Medical and Industrial Research Institute of Nuclear Science and Technology is in charge of non-formal training courses especially in pet radiopharmaceuticals new cyclotron (AEOI 2015).

3- Medical offices and centers practicing nuclear medicine: The first g camera for SPECT procedures was installed in the nuclear medicine department of Army Hospital No. 502 in Tehran in 1992. Today, 164 g cameras have been purchased for the country and all 30 provinces of Iran have at least 1 nuclear medicine unit. Of the 158 nuclear medicine departments in the country, 43.6% are owned by the public sector and 56.4% by the private sector. Eighty departments 68.4% of the departments are established in hospital settings, and 31.6% are free-standing centers. Of the 164 installed g cameras, 85 (51.8%) are owned by the private sector and 79 (48.8%) by the public sector. Seventy-four g cameras (45.1%) are installed in hospital settings, and 90 (54.9%) are in free-standing imaging centers. At the present time, the number of nuclear medicine departments per million inhabitants is 1.36, and the number of g cameras per million inhabitants is 2.2. In 2009, 81 g cameras (49.3% of the nation's total) had been installed in Tehran, representing 54 nuclear medicine departments (46.2% of the nation's total). Iran, with almost 75 million individuals, has very few SPECT/CT machines and no PET or PET/CT. Official sources have estimated overall insurance expenditures on medical imaging by the 3 government insurance institutes in fiscal year 2007–2008 at the equivalent of about US$96 million. Nuclear medicine's share was: US$9 million or 9.5% of overall expenditures for medical imaging. (Gholamrezanezhad A 2010).

4- And finally, Ministry of Health and Medical Education issues the certificates of good manufacturing practice for the firms producing the medical radioisotopes. There are organizations in charge of issuing regulations and permit for imports. It encompasses the Medical Equipment Office of the Iranian Ministry of Health and Medical Education (the only regulatory body issuing permission letters for importing and installing imaging equipment throughout the country), the Iranian Society of Nuclear Medicine, and 3 major government insurance organizations which collectively provide health coverage to .90% of the country's population.

The Achieved Functional Pattern:
Each major player has different functions which are categorized, here, according to Hekkert (Hekkert 2007):

F1-Entrepreneurial Activities: Although the nuclear industry is concentrated in the hands of State organizations under auspices of AEOI, like the Pars Isotope Company, in the downstream, there are more than hundred companies and organizations associated with the nuclear medicine, which are active in learning and experimenting innovative medical research (D. B. Amir Reza Jalilian 2016).

F2-Knowledge Production: Iran is the 28th country in the world and the third country in the region publishing scientific papers in nuclear medicine, right after Turkey and Israel.

Table (2): The rank of Iran in the scientific publication on nuclear medicine and imaging in the region, Source: (SJR databank 2017).

1996-2015

Display countries with at least 0 | Documents | Apply | Download da

	Country	Documents	Citable documents	Citations	Self-Citations	Citations per Document	H index
1	Turkey	10149	9302	83683	13379	8.25	79
2	Israel	3860	3603	61961	5686	16.05	94
3	Iran	3042	2888	15685	5619	5.16	44
4	Egypt	1941	1881	12332	1573	6.35	45
5	Saudi Arabia	1036	973	9134	638	8.82	41

In 2009, following a contract between IRI Deputy President for S&T and Atomic Energy Organization of Iran, a mega project of producing several radiopharmaceuticals was designed and Nuclear S&T Research Institute and Pars Isotope Company was designed to build the research teams and conduct the research. In order to have a plan for making the most needed radiopharmaceuticals, a survey was conducted in 20 nuclear medical centers and medical universities. First, a list of 30 most needed radioisotopes was compiled, then, it was narrowed down to the 20 technically feasible according to the level of national technological capabilities. To attain this goal, a road map was designed and financed by IRI Deputy President for S&T with an amount of 40 billion Rials equal roughly to 1 million Dollars. According to the roadmap, 17 research teams were built and led by a central leadership and 7 team managers. The different teams were tasked with acquiring and creating and building the core and enabling technologies and infrastructures, including clean rooms, clinical trials, packaging, handling, delivery and standardization of the process.

F3-Technology Diffusion: The underlying infrastructure of the research projects is a network of Nuclear S&T Research Center and the Pars Isotopes Company with nuclear medicine research centers of Iranian universities as research partners. According to the AEOI documents, 32 Ph.D. candidates were working on dissertations in this projects supervised by 20 university professors. This network has shaped

a strong triple helix with three actors of university and industry and state in Iran.
On the other hand, during the last previous 4 years, four international conferences in which the radiopharmaceuticals specialists from 14 countries shared their scientific knowledge have been held. These events helped to diffuse the latest technological achievements in Iran.
Moreover, annual symposium of nuclear medicine is another event which is held, yearly since 1995. It is the gathering of nuclear medical researchers and practitioners in Iran. From the 2007, the symposium was held at the international level inviting international lecturer.

F4: Research Guidance: Due to the security aspects, the governance of the radioisotope R&D and production is in the control of the AEOI which is, in turn, monitored by IAEA. The high public expectation is another factor which affects the production of radioisotopes in Iran.

F5.Mobilization of Human and Financial Resources: The high national expectation paved the way for galvanizing the material and human capital; public funding was mobilized and academic and technical training was designed in the universities and research institutions.
The quantity of the admitted Ph. D students in nuclear engineering and radio medicine is exceptionally high (around 10 students for each university) and in the current year, Azad University has accepted 18 students. The national policy promotes the increase of the quantity of the Ph. D, students in nuclear technology and has established some incentives e.g. student loans and grants for student transfer from other disciplines. Other than academic education, there are other centers for job training and educational services; the department of medicine of the Institute of Agricultural Research, Medical and Industrial Research Institute of Nuclear Science and Technology is in charge of non-formal training courses especially in pet radiopharmaceuticals new cyclotron (AEOI 2015).There are 3 universities which offer fellowships and residencies for nuclear medicine: The Tehran university of Medical science, the Imam Reza University, hospital of Mashhad medical school and Taleghani center of Shahid Beheshti university. (Razaghi 2011).

F6.Market Formation: There are around 160 centers of nuclear medical centers in Iran in which more than 1300 nuclear medical specialists work. This market is growing by 23 percent about two times more than the world rate. According the national statistics the local market's need is met by indigenous industry. The regional markets will be open when the local production meets global standardization.

F7.The legitimization of the technology and Standardization: The international sanctions had charged politically the atmosphere with nationalistic sentiments during 2000-2013. That helped this industry to legitimize research and development of radio-pharmaceuticals high costs. The medical centers, facing numerous patients with cancerous and non-cancerous disorders, could not use foreign resource. Therefore, they championed the growth of the industry and the strong foundations like the foundation of war martyrs and injured soldiers with high political status advocated their cause. Consequently the political issues and the international sanctions had major role in the legitimization of this sector.
Within the national market, the AEOI is responsible for the establishment of regulations for nuclear and radiation safety (under a 1989 act), licensing facilities, and supervising. The Iran Nuclear Regulatory Authority (INRA) is responsible for regulation and safety, as well as monitoring, legal compliance and radioactive waste management. It is under the AEOI and maintains a close relationship with its Russian counterpart named Rostechnadzor. (World Nuclear News 2014).
In the end of this section, structural and functional matrix is developed in order to review the structure and functions of the nuclear medical technology in Iran:

Determining the inducer and blocker of the catching up process:

The international sanctions have played as an inducer for the functionality of the SIS at some degrees. The sector is highly motivated to innovate and learn by independent research and development and trial and error and accumulate

Table3: Structural and functional matrix of Radio Pharmaceuticals agents

Function/ players	State(Vice Presidency for S&T)	AEOI	NS&T Research Center	universities and training centers	Pars- Isotopes and other forward backward industries	nuclear medical centers and hospitals	Medical regulatory institutions (Ministry of Health	Medical Networks
Entrepreneurship						•		
Policy Design-Goal Setting		•	•					
Knowledge production				•	•			
Knowledge diffusion	•			•				•
Mobilization of Financial Resource	•							
Mobilization of Human Resource				•				
Market Formation	•						•	
Legitimization		•					•	

technological capabilities. Knowledge production has not been based on market prices and is not commercialized for private benefit. The industrial strategy was set for the import substitution at virtually any costs.

International sanctions have important negative consequences, too. The whole learning process has occurred in an isolated bubble. It has not had the opportunity of interaction with the GVC technology leaders or competes with countries downstream like Turkey a neighboring country with has extensive connections with global knowledge networks in Europe and USA. The system is not approved by the international standard institutions and does not have necessary approvals of efficiency, quality control and safety and security from the GVC leaders, increasingly demanded in the world trade of radiopharmaceuticals. Due to the sanctions, the clinical trials of the radiopharmaceuticals have not been registered and documented in the technical portals. Security concerns have isolated the main labs and many facilities were under the export control (Iranwatch 2015) .

Consequently, the paper can conclude that the international sanctions worked as an inducer in the stages of infancy and early growth due the influence they have had on the overall national atmosphere (F7), the priority setting in the national agenda (F4), the mobilization of resource and manpower (F5) . However, the same factors (international sanctions) worked as blocker of the dynamics of innovation system since it has impeded the process of international standardization and regional market entry. In the jargon of Keun Lee and Chaisung Lim (Lim 2001), it has helped to reach technological catching up, yet blocked its outreach to the regional market, since it does not have the international standards.

According to Pars Isotope reports: there are three types of products made in Iran:

1-Cold Kits: the one which are in the mature phase of technological life cycle. There are no problems with technological complexity, yet they require more modern infrastructure like new clean room, heater magnet and full automatic dispenser. This technology is required to acquire GMP certification to enter to the regional market.

2-Generators: As explained the inputs are imported from Russia although up till 2011, Iran had to produce them despite the high cost and complexity of the process. This division needs

also new and more modern clean rooms and hot cells and requires to get international standard certification
3-Cyclotron -Solid and liquid target: this area is also in need of international standard and the biggest challenge is the lack of GMP certifications for exporting the radio-pharmaceuticals.

Conclusion

After the Revolution, Iran was practically left outside the loop of GVC, but it was determined to have an indigenous industry of radiopharmaceuticals without the industrial countries' blessings. In isolated atmosphere, the domestic learning has been highly motivated, and local value chain of radiopharmaceuticals gradually emerged and flourished in the country in this practically isolated atmosphere. The industry which twenty years ago was practically non-existent, by using successful strategy of learning rents and heavily investment in manpower, now has reached technological catching up status in some products like technetium-99 generators and can manage to meet the growing local demands at an accelerating rate. During these years, the strategy was import substitution, the learning pattern was mainly based on science technology and innovation (STI) and reverse engineering, experimentation and learning by interaction with very limited knowledge sources.
Iran is now poised, to stretch its market to neighboring countries and benefit from the geographical and relational proximity it has within the region. It proves to be not an easy task, however. To attain this objective, it needs to establish a costly infrastructure and update different laws and regulations like FD, intellectual property right and create the right atmosphere for entrepreneurship, a process of institutional catch-up which requires a separate study.

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