

Patent Policy

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Submission date: 10-Mar-2022 04:58PM (UTC+0700)

Submission ID: 1780975312

File name: A.1.1.5_Artikel_Patent.pdf (160.57K)

Word count: 7604

Character count: 40636

1 Research Article: 2020 Vol: 23 Issue: 5

Patent Policy on the Pharmaceutical Sector in Indonesia

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Abstract

This study aims to explain the regulation of inventions that are considered against the religion in Indonesia and analyze the patent policy on pharmaceutical fields after the enactment of the Patent Law and the Certified Halal Product Law in Indonesia. The research reveals that first, the context of the creation of the provisions of an innovation that is considered against the religion in Indonesia is a manifestation of the duty of the state in providing protection of people's rights to guarantee a safe and secure life in worship in accordance with their religious teachings as determined in the Basic Law Second, 1945. Secondly, it is appropriate to synchronize the provisions of an innovation considered against religion in Indonesia between Law No 13 of 2016 on patents and Law No 33 of 2016 on certified halal products, because the State is obliged to provide protection and assurances in respect of halal products consumed and used by the public. Certified Halal goods should be carried out in compliance with the values of security, fairness, legal certainty, accountability and openness, quality and effectiveness and professionalism, taking into account that all Indonesians are religious, with 207 million Muslims, 87.2%, Protestant Christians 6.9%, Catholic Christians 2.9%, Hindu 1.7%, Buddhists.

Keywords

Halal Policy, Invention, Pharmacy, Patent.

Introduction

8 Article 1 number 1, Law number 13 of 2016 on Patents states that a patent is an exclusive right given by the government to an inventor for a certain period of time for his innovations in technology, whether the proprietor of the patent invents it on his own or gives permission/license to other parties to use it. A patent is divided into 2 (two) forms, namely patents and simple patents, as a technology defence form for both goods and processes. A patent issued for new inventions shall consist of an innovative technique and may be applied in the field. In comparison, with any invention, a utility patent is granted, covering the latest process or product innovations, which can be applied in the industry (Sudarwanto and Handayani, 2019) The legislation also allows for an invention and must comply with a range of criteria, such as innovation, inventiveness and industrial implementation (Aris et al., 2015). However, a patent right may not be given to any of those three-requirement inventions, because they would comply with the requirements laid down in Article 9 of the Non-Patent Innovations Patent Law. One of them, as mentioned in Article 9 letter a, is an invention that is contrary to religion, which states that a non-patent story involves a method or product that is declared, used or introduced contrary to laws, religion, public order or decency (Padmawati et al., 2019).

The clause also becomes the key point of an innovation in which an innovation, since it is against religion, cannot be awarded a patent. "Announcement", "use" and "implementation" are the terms. This provision is the responsibility of the government to protect and guarantee all religious believers to worship and practice their religious teachings relevant to the halal products of the nation. Most Indonesians are Muslim, with 207 million followers (87.2 percent), according to the Indonesian Information Portal results. At the same time, the remaining 6.9% are Protestant Christians, 2.9% are Catholic Christians, 1.7% is Hindu, 0.7% is Buddha, and 0.05% is Confucians (Jaelani et al., 2019). The knowledge reveals that the majority religion practiced by Indonesians is Islam. Islam, therefore, deeply affects the social life of Indonesia. These inventions do not contradict patent inventions with Islam as the majority religion in Indonesia, and, of course, the Muslim hopes for Islamic sharia inventions (Elasragh, 2018).

In general, halal items, both the product and the procedure, are required by the demands of Islamic sharia. Even before this amendment, Regulation No 33 of 2014 on Certified-Halal Product was constitutionally ratified by the government to manifest the duty of the government to protect the human rights of life insurance and to provide safe worship in accordance with its religious teachings, as set out in the Constitution of the Republic of Indonesia of 1945 (Karjoko et al., 2020). Pharmaceutical innovations are one of the most fragile halal innovations. Medicine is referred to as a design because it is a technical pharmaceutical product for solving community problems, especially health care. Article 1 Number, 8 Health Regulation Number 36 of 2009 specifies that medicinal products are materials or a mixture of materials, including biological products, used for the purpose of affecting or investigating physiological processes or pathological conditions in the field of human, prevention, recovery from treatment and improvement of health and contraception (Murwani and Murtini 2009).

Based on the above provisions, the medicine can be distinguished based on its function, namely condition in the diagnosis, prevention, cure recovery, health improvement, and contraception for humans. One of the Indonesian prevention-market medicines is a vaccine. Measles-Rubella (MR) vaccine is a vaccine or toxoid (an altered and attenuated bacterial toxin) to increase one's immunity from Measles and Rubella. Measles Symptoms could be high temperature (fever), redness (rash) with coughing and colds, and conjunctivitis (Zailani et al., 2010). They can lead to complications in pneumonia, diarrhea,

and meningitis and even cause death. Regarding MR vaccine immunization, there are pros and cons in its use since non-halal ingredients, pig derivatives, are indicated to be used in vaccine making. MR vaccine is used to protect against measles and rubella (Lever and Miele, 2012). Both are easily transmitted and dangerous diseases since they can cause permanent disability and death. The number of reported measles-rubella suspects in the last five years in Indonesia drastically increases that the number of suspects was 12,943 in 2014, 13,890 in 2015, 12,730 in 2016, 15,014 in 2017, 2,398 until July 2018. In the last five years, the total reported cases were 57,056 suspected cases with 8,964 positive measles and 5,737 positive rubella (Aris et al., 2015).

Therefore, the Indonesian Ulema Council responded by issuing Indonesian Ulema Council Fatwa Number 33 of 2018 on the Use of MR Product Vaccines from the Serum Institute of India (SII) for Immunization. This fatwa confirms that the use of vaccines with the element of pigs and their derivatives is haram. Still, in an urgent case, no halal and holy MR vaccine has been found (Alzeer et al., 2018). There is information from competent and trusted experts about dangers of not being immunized and the absence of halal vaccines. The use of the MR vaccine is permitted (mubah) (Kang et al., 2018). Based on the Intellectual Property Database of the Indonesian Ministry of Law and Human Rights, MR vaccine SII products have not yet been registered with a Patent (Kuncoro et al., 2019). The fatwa specifically mentions SII, whereas the number of vaccines patented in Indonesia based on the Intellectual Property Database of the Indonesian Ministry of Law and Human Rights is 500 inventions. Although the MR vaccine has not yet been registered with a patent, there is a similar vaccine product registered and given a patent to Sanofi Pasteur French citizen with patent number IDP000061348 which acts as a patent holder for Japanese encephalitis vaccine, measles, mumps, rubella, which uses a pig enzyme in the form of trypsin as a catalyst in the vaccine manufacturing process (Jaelani et al., 2020).

As it is known that the pig is one of the forbidden animals in Al-Quran Surah Al-Baqarah verse 173, which means that Allah only forbids you carcasses, blood, pork, and animals that (when slaughtered) are called (names) besides Allah whoever is in a state of compulsion (eat it). At the same time, he does not want it and does not exceed the limits; there is no sin for him. Indeed Allah is merciful, merciful, and merciful. Then, if the paragraph is related to Article 9 letter an of the Patent Law, it could be that an invention that in the process of using non-halal material makes the design unable to be granted Patent protection and violates Article 9 letter an of the Patent Law because it is against the religion (Jaelani et al., 2020). On the other hand, the use of the pig as a catalyst in making a medicinal product has long been done. Since the 1940s, researchers have found that trypsin can catalyze microbial growth in culture media so that the results obtained can be more in a shorter time. After much research, it was found that trypsin from pigs could be used as a catalyst in making vaccines (Prasetyo et al., 2019). One factor that causes the use of pig trypsin as a catalyst in making drugs or the polio vaccine is the limited other sources that can be used as a substitute catalyst for the trypsin pig (Jaelani et al., 2019). This research will focus on the regulation of inventions that are considered against Indonesia's religion and analyse the patent policy in the pharmaceutical sector in Indonesia after the entry into force of the Patent Law and Certified Halal Product Law in Indonesia.

Research Method

This research is normative law and prioritizes library research. According to Leonard, normative legal research is a study of legal principles, legal systematic, legal synchronization, legal history and legal comparison (Leonard et al., 2020). This research approach used the statutory approach, historical approach and conceptual approach. The legislative approach was carried out by examining the laws and regulations relating to patents. The historical approach was carried out by examining the legal and sociological background and argumentation regarding the standardization of patent grants (Rachmi et al., 2017). Then, the conceptual approach was carried out by exploring the concept of invention that does not against the religious values, as the first precepts of representation, namely the almighty God. The research design or legal materials used secondary data sources consisting of primary legal materials, secondary legal materials, and tertiary legal materials (Kuncoro et al., 2019).

Results and Discussion

Theoretical Reasons for the Urgency of Halal Pharmaceutical Products in the Patent Application

Regulation of halal products in Indonesia is spread in several laws, including Law Number 8 of 1999 concerning Consumer Protection, Law Number 18 of 2009 on Animal Husbandry and Animal Health, Law Number 18 of 2012 concerning Food, Law Number 33 of the Year 2014 regarding Guarantee of Halal Products, Law Number 13 of 2016 regarding Patents. Article 9 letter an of Law Number 13 of 2016 concerning Patents states that inventions that cannot be granted a Patent include processes or products whose announcement, use, or implementation is contrary to statutory regulations, religion, public order, or morals. This provision is a measure of the state obliged to provide protection and guarantee to every religious believer to worship and carry out his spiritual teachings regarding the halal products consumed and used by the community (Elasragh, 2018).

The reason is also in line with the theory of public interests (public interests theory), which is one of the reasons for state intervention in the regulation-making, in the sense that public interests are not born out of special requests or claims but are born out of public sentiment and supported by public interest organizations. Because there is support from the public interest, related institutions are asked to make the following regulations. Croley explained that in the perspective of public interest, the decision-making process to make regulation is entirely based on policies for the community's benefit and welfare, and not as an attempt to regulate in the dark to avoid openness. The purpose of regulation in public interest theory is not for narrow interests or social interests packaged to benefit specific groups, namely rules that support narrower constituents (Bukhari et al., 2020).

As Haque explained that the basis for the economic justification of regulation is the existence of a market failure. In this case, market failure is prima facie evidence to intervene with rules in the public interest. From the explanation above, it can be seen that public interest theory is the benefit, interest, and utility of the public, which must get recognition and protection from the state. Recognition and protection of welfare, interest, and utility justify state intervention through regulation (Haque et al., 2015). Related to this research are the benefits, claims, and benefits of consuming halal products for Muslim consumers who must receive recognition and protection from the state in the form of regulations. Based on the views of Haque above, the law in the economic sector (protection of Muslim consumers to obtain halal products) serves to correct market failures for the benefit of the public (public interest) (Soon et al., 2017).

As explained by Haque, one reason that justified and justified state intervention through regulation in the economic sector is information asymmetries. This is related to the assurance of Muslim consumers in consuming halal products. Halal certification and labelling become consumer information, so there is no misleading information for Muslim consumers. As we know, information asymmetries on the halalness of a product make it difficult, even impossible, for consumers to evaluate a product's halalness (Lever and Miele, 2012). Minimal information on the halalness of products affects consumer objectivity in choosing products, so regulations on detailed and accurate information about halal products are needed so that consumers can access halal products.

About pharmaceutical products, the question is, should each product classified according to its type be certified and labelled? The classification of product types required in this paper is to organize the kinds of mass-produced (massive) and non-massive (non-massive). Knowledge of this type of product is related to certification and product labelling (halal), which will be discussed later (Jaelani et al., 2020).

Talib et al. (2016) stated that the product characteristics that must be certified and labelled are experience characteristics and credence characteristics. Furthermore, Talib divided product characteristics into three elements: search characteristics, experience characteristics, and credence characteristics. The distribution of these characteristics is based on consumer efforts to detect, test, evaluate, and validate products. When viewed from these criteria, pharmaceutical products enter credence characteristics that require halal certification. Certification and labelling ensure that the products being traded do not cause information asymmetries and do not mislead consumers (Talib et al., 2016). Likewise, halal certification and labelling on products is a communication tool to provide information and a means to track the halalness of a product for consumers and ensure that the products being traded do not mislead consumers. More fundamentally, the certification and labelling of a product change the consumer's view of work from experience characteristic to search characteristics and from credence characteristic to explore aspects. Consumers can choose products with their preferences, based on honest and credible information, which will create a fair magazine (Jaelani et al., 2019).

In line with these thoughts, halal certification and halal labelling on food products, consumers aim to determine the halalness of the work from experience characteristics that can be evaluated after buying and consuming, because only based on experience, it becomes search characteristics that can be validated by consumers through a visible label, and of credence characteristics that consumers cannot evaluate, because they do not have technical expertise, become search characteristics that can be validated by consumers through a visible label. Thus, government action, regulation, intervention, and policies on the market are needed for products with characteristic credence claims (Alzeer et al., 2018). Consumers cannot evaluate, validate, and test the product's halalness, even after consuming the work. Consumers only rely on brands and labels to determine product quality as a credential signal to producers. Conversely, mislabelled credence will erode consumer confidence in these products (Jaelani et al., 2019).

Regulations on Inventions Considered Against the Religion in Indonesia

The beginning of formation of Article 7 letter a of the Law of the Republic of Indonesia Number 14 of 2001 on Patents, as replaced by Article 9 letter a of the Law of the Republic of Indonesia Number 13 of 2016 on Patents is a legal adjustment between international law especially in the World Trade Organization (WTO) which contains instruments governing IPRs protection for WTO member countries, namely agreement on trade aspects related to Intellectual Property Rights (Agreement on Trade Related Aspects of Intellectual Property Rights hereinafter abbreviated to TRIPs) with the identity of the Indonesian people as a Pancasila country (Prasetyo et al., 2019).

Patents as one part of the scope of IPRs that get legal protection through TRIPs must be one of the instruments stipulated in the national regulations of each WTO member country, including Indonesia. Acceptance and participation of TRIPs which forms part of an Agreement on the Establishment of the World Trade Organization as ratified by Law Number 7 of 1994 on Ratification of the Agreement Establishing the World Trade Organization. One of the functions of TRIPs is to regulate the protection of patents in accordance with the needs of each member country, provided that they do not override or forget the basic principles that exist are the TRIPs agreement. The basic principles of the TRIPs agreement are as follows: (Padmawati et al., 2019)

1. When member countries formulate or amend their national laws and national regulations, as well as adopt measures needed to protect and promote the public interest in sectors which are important for carrying out development in the socio-economic and technological fields of member countries, it is hoped that these actions can take place consistently with the provisions of the TRIPs agreement made. It is done by setting minimum standards to provide protection and law enforcement of IPRs in participating countries.
2. They must continue to be consistent with the provisions of this Agreement, necessary to be able to tackle the misuse of intellectual property rights by right-holders or resorts to unreasonable practices in inhibiting trade or international technology transfer processes.
3. Each participating country must provide protection to citizens of other participating countries. Member countries are required to provide the same intellectual property protection to other member countries.
4. Rigorous law enforcement is accompanied by a dispute resolution mechanism, which is followed by the right for the injured country to take action in a cross manner.

Historically, exceptions to inventions which cannot be granted patents have been included since the first patent law was issued, namely in 1989 through the Law of the Republic of Indonesia Number 6 of 1989 which subsequently changed with the issuance of the Law of the Republic of Indonesia Number 13 1997 on Amendment to Law Number 6 of 1997 concerning Patents (1997 Patent Law). The 1997 Patent Law is a law that was issued as a consequence for Indonesia as a WTO member country that has the obligation to make adjustments to its national law with the provisions of the TRIPs. Nevertheless, in 2001 the Patent Law was replaced by Law of the Republic of Indonesia Number 14 of 2001 on Patents. Through the Patent Law, it is stated that exceptions to the invention that can be granted in connection with an invention that is contrary to religion were first issued and are still maintained in Law Number 13 of 2016 on Patents currently in force. In Act Number 13 of 2016 on Patents regulating inventions that cannot be granted a patent can be seen in Article 9 which is as follows: Inventions which cannot be granted a Patent include: (Wombwell et al., 2015)

1. Processes or products that are announced, used or carried out in conflict with statutory regulations, religion, public order or decency;
2. Methods of examination, treatment, treatment and/or surgery applied to humans and/or animals;
3. Theories and methods in science and mathematics;
4. Living things, except micro-organisms;
5. Biological processes that is essential for producing plants or animals, except nonbiological or microbiological processes.

As a current Patent law, the provisions in Article 9 above are maintained and have not experienced significant changes from the provisions in Article 7 of Law Number 14 of 2001. Changes that distinguish between the two provisions are only in the addition of an explanation of Article 9 letter b that is related to the purpose of the examination method which is a diagnostic method and a treatment method which is a method of treatment for medical which was not previously explained in Article 7 letter b of the 2001 Patent Law. For Indonesia which has a culture that is different from other countries, it needs an appropriate regulation with what is in the community. It is because sociologically the majority of Indonesia's population is a religious community. It can be seen in the static followers of Islam as many as 207 million people or equal to 87.2%, while the rest are Protestant Christians as much as 6.9%, Catholic Christians as much as 2.9%, Hindu 1.7%, Buddhism 0.7% and Confucians 0.05%. As a state with the ideology of Pancasila, it is deemed necessary to formulate legislation in the field of PRs especially patents in accordance with the ideology of the nation. Pancasila as the basis of the state and the source of state law is a mandate from the opening of the 1945 Constitution of the Republic of Indonesia in the fourth paragraph (Jaelani et al., 2020).

In terms of making laws and regulations, Article 2 Paragraph (2) of Law Number 12 of 2011 on the Formation of Laws and Regulations explicitly states that Pancasila is the source of all sources of state law. In the dynamics of the social process, Pancasila is realized in various fields of life, also in the field of law. The application or realization of Pancasila in the field of legal life fosters the legal provisions imbued or colored by Pancasila. The entire legal system as a system of positive legal rules which is the elaboration or application of Pancasila in the field of law, can be called the Pancasila Law. Pancasila Law as a positive law grows from within and/or is made by the Indonesian people to regulate and realize fair order in the life of the people in Indonesia (Kuncoro et al., 2019).

That formulation of Pancasila is in Indonesia's positive law constitutionally, in effect, and binding on all state institutions, community institutions, and every citizen, without exception. The formulation of Pancasila imperatively must be carried out by the Indonesian people in the life of the nation and state. Each of the Pancasila precepts is an integral whole, which supposes and interlocks. God is upheld in the life of the state, but placed in the context of an egalitarian family state, which transcends the understanding of individuals and groups, in line with a vision of humanity that is just and civilized, national unity, deliberative democracy that emphasizes consensus, and social justice for all Indonesian people (Jaelani et al., 2020).

In the system of statutory regulations in Indonesia, the overall system of legal norms of the Republic of Indonesia as a whole is a hierarchical (tiered) system. Pancasila as the basis of the state in Indonesian law is a source because it is a basic norm (staatsfundamental), which then successively verfassungsnorm or the 1945 Constitution, grundgesetznorm or MPR decree, as well as gezetznorm or Law. Pancasila is the essence of staatsfundamentalnorm, Consequently Pancasila is a source for the formation of articles in the 1945 Constitution, is a source and basis for the formation of regulations under it. So far, as a member of the WTO, Indonesia has made various adjustments to the provisions of TRIPs into national legislation, especially in the field of patent protection. In accordance with Pancasila values, this is seen in Article 9 letter a Law of the Republic of Indonesia Number 13 of 2016 concerning Patents (Padmawati et al., 2019).

Patent Policy on the Pharmaceutical Sector in Indonesia

Vaccine was widely discussed because it was considered to have pork content in it so it became a debate related to halal or haram. Pros and cons regarding the use of vaccines begin with the polio vaccine. According to Iskandar as the Director of Planning and Development of PT. Bio Farma in 2008, he stated that the production of polio vaccine in Indonesia uses a pig enzyme known as trypsin (Porcine-derived trypsin) as a catalyst in the manufacturing process (Tieman and Maznah, 2014). The manufacture of vaccines containing pigs has been started since the outbreak of polio cases in 2002 so that a treatment is needed in an effort to prevent it from spreading. The handling has been rejected by the Indonesian Ulema Council (MUI) which states that the polio vaccine is legally prohibited, because the standardization of its manufacture contains najis (impure objects) namely pigs. In addition to these problems, the 2009 meningitis vaccine is very troubling for pilgrims and umrah pilgrims (Murwani and Murtini 2009). Because the Belgian meningitis vaccine product imported by the Indonesian Ministry of Health in the process of its production is in contact with ingredients in the form of enzymes from the pancreas of pigs and glycerol from lard. Therefore MUI issued MUI Fatwa Number 5 of 2009 which confirmed that the meningitis vaccine was haraam, because the standardization of its manufacture was in contact with impure objects in the form of enzymes from pig pancreas and glycerol from lard. However, in 2010 the public was able to feel calm because there was another alternative to the replacement of a vaccine made in Belgium, namely a vaccine produced by a company from Zhejiang China and through MUI Fatwa No. 6 of 2010 concerning the Use of Vaccines for Pilgrims or Umrah the meningitis vaccine made in Zhejiang China was considered halal because in the production process is not polluted with unclean pigs (Padmawati et al., 2019).

In 2018 it appeared a problem of the use of MR (Measles Rubella) vaccine against measles produced by SII (Serum Institute of India) using gelatin originating from pork skin and trypsin originating from pig pancreas and material originating from the human body, namely human diploid cell. Therefore MUI responded by issuing MUI Fatwa Number 33 of 2018 regarding the Use of MR Product Vaccines from the Serum Institute of India (SII) for immunization. This fatwa confirms that the use of vaccines utilizing the element of pigs and their derivatives is haraam, but in a condition of compulsion, there has not been found a halal and holy MR vaccine and there is information from competent and trusted experts about the dangers posed by not being immunized and the absence of halal vaccines, then the use of MR vaccine is permitted (mubah) (Lestari and Irene, 2020) (Table 1).

No Patent	Applicant	Protection	
		Date of Giving	End up
IDP000046231	Tim HIRST, dkk	2017	2032
IDP000058077	Radosevic, dkk	2019	2034
IDP000052619	Saville, dkk	2018	2033
IDP000052312	Hamid, dkk	2018	2032
IDP000046752	Ohsawa	2017	2030
IDP000061348	Bouckenooghe,dk	2019	2033

Source: Intellectual Property Database of Ministry of Justice and Human Rights 2019

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Based on the Intellectual Property Database of the Indonesian Ministry of Law and Human Rights, the MR vaccine for SII products has not yet been registered with a Patent. The fatwa specifically mentions SII, whereas the number of vaccines patented in Indonesia based on the Intellectual Property Database of the Indonesian Ministry of Law and Human Rights is 500 inventions. Although the MR vaccine has not been registered with a patent, there are similar vaccine products that have been registered and granted a patent, including: (Spiegel et al., 2012)

Patent number IDP000046231 is an invention related to the vaccine field. More specifically this invention relates to the composition and methods for enhancing immune responses induced by vaccines, which include vaccines targeted at infections and secondary conditions associated with influenza infections. While the Patent number IDP000058077 shows that the invention provides influenza hemagglutinin stem domain polypeptides. The patent number IDP000052619 shows that an invention related to the composition of a vaccine that is useful in the method of protecting human subjects against dengue. Patent number IDP000052312 shows that the invention is immunogenic consisting of human Enterovirus A antigens, human Enterovirus B, human Enterovirus C, human Enterovirus D. Patent number IDP000046752 shows that an invention that provides isolated peptides having an amino acid sequence SEQ ID NO: 34 or fragments thereof, which binds to HLA antigens and induces cytotoxic T lymphocytes (cytotoxic T lymphocyte-CTL) and patent numbers IDP000061348 shows an invention related to a method of vaccination against Japanese encephalitis (JE), measles, mumps and rubella which consists of using the MMR vaccine and the use of live attenuated JE vaccine or obtained from cell culture that is deactivated simultaneously to patients in need of patients who need it.

If related to Article 9 letter a of the Patent Law, inventions which in the process of using non-halal material make the invention unable to be granted Patent protection and violate Article 9 letter a of the Patent Law because it is contrary to religion. The standardization is used as a benchmark for special drug products in the form of vaccines is haram and halal (Harimurti & Jaelani, 2019). Halal is something that if used does not violate the provisions of Islamic law, while haram is something that God forbids to do with strict prohibitions, where people who violate it are threatened with punishment by Allah in the hereafter. In general, the meaning of halal is a case or act that is permitted, or justified by Islamic law, while haram is a case or action that must or is not permitted by Islamic law (Bukhari et al., 2020). In detail something forbidden comes from: (Aris et al., 2015).

1. Pigs, dogs, and children born from their second marriage;
2. Carcasses except fish and grasshoppers;
3. Disgusting animals such as worm, fleas, leeches and so on;
4. Animals that have fangs;
5. Animal with hooved claws that eat their prey by pouncing and grabbing;
6. Animals which are forbidden by Islam to kill him such as bees, hud-huds, frogs and ants;
7. Meat cut from halal animals even though they are still alive;
8. Toxic and dangerous animals when eaten;
- 30
9. Animals that live in two worlds such as turtles, crocodiles, monitor lizards and so on;
10. Blood, urine, feces and placenta;
11. Animal oils, fats, and bones mentioned above;
12. The animal slaughtered is not in the name of God;
13. Khamr (liquor).

The rules that apply to medicines are basically nothing special. Because, it is made from materials consumed by humans such as plant extracts, animal extracts, synthesis and semi-synthesis, minerals, biology, microbes, and viruses, and can also be a mixture of these ingredients. Therefore, Halal and Haram rules that apply in food, both food and drinks, also apply to medicines (Ahmad et al., 2011) In making medicines, illicit ingredients both derived from plants (vegetable), animals, or a mixture of both should be avoided. In addition, the material must also be holy, clean from najis. If the material comes from chemical elements (synthetic) then the material must be safe, not harmful to humans. Meanwhile, in the production process we also must avoid unclean or impure materials. Thus, the factory as a place to produce it only produces halal medicines so that the products are not contaminated by unclean or impure materials. If the factory also produces illicit products, then there must be a process of washing equipment that is used in accordance with Islamic law (Soon et al., 2017).

Drugs are all substances, both synthetic chemicals and natural substances which are in proper dosages able to affect the body's organs to function normally. Components used for the manufacture of drugs consist of active ingredients of drugs or nutritious substances and pharmaceutical ingredients. Active drug ingredients are the main substances that have the effect of treating or preventing an antipretic disease or fever, anti-infectious, anti-histamine, etc., while pharmaceutic ingredients are additives that open drugs which together with the drug are made into pharmaceutical products (Soon et al., 2017). Active drug ingredients can come from plants, animals, microbes, synthetic chemicals and human body parts. Active ingredients derived from plants can come from some or all parts of plants by means of solvent extraction or processed by fermentation. The rule of halal is seen from the added ingredients of the active ingredients of the drug (Jaelani et al., 2020).

Active ingredients derived from animals are generally classified as compounds such as proteins, amino acids, vitamins, minerals, fatty acids and their derivatives, enzymes, and others. If it comes from illegitimate animals, then it is also illegal to consume it, whereas if it comes from halal animals, it is necessary to further study the procedure for its slaughter (Wombwell et al., 2015). Active ingredients derived from microbes such as statins, amino acids, hormones and others, the halal is highly determined by the media used such as refresher media, propagation media, and production media. In addition, the

halal status is also determined by the supporting material used and also the condition of the post-fermentation material such as the use of activated carbon for the refining process, and so on. Based on these criteria when looking at the use of catalysts in the pharmaceutical world that contain pork even though the catalyst content at the end of the drug manufacturing process will not leave any residue or in other words there will be no pig element, so it can still be called as an illicit medicinal product. Seeing from the perspective of patent law that applies in Indonesia today, if a product is considered haram then it becomes a question whether the invention that produces a product in the form of medicines, especially vaccines, can still be granted a patent as stipulated in the 2016 Patent Law (Wibowo et al., 2019)

Based on the aforementioned provisions, if the invention in the field of medicines contains the element of pigs, the applicant must explain in the Patent application documents what content is contained in medicines or vaccines including what ingredients are used during the production process or its manufacture. Inventions that are requested to be granted a Patent that has been proven in the substantive examination process, there are substances or substances which are considered haram based on Islamic legal principles both in the manufacturing process and the final results in the form of medicinal products or in this case in the form of vaccines cannot be rejected by the DJKI. to be granted a Patent (Elasragh, 2018). The formulation of provisions of inventions that are contrary to religion in Article 9 letter a of the 2016 Patent Law are universal, which means that even if the invention that produces a product in the form of medicines or vaccines is not in accordance with Islam, according to other religions that are embraced and recognized in Indonesia, it does not assume that the invention is requested to contradict the contents of their respective religious teachings, the invention cannot be rejected or in other words the provisions of the invention that are contrary to religion must be in conflict with all religions namely Islam, Christianity, Catholicism, Hinduism, Buddhism, and Confucianism as well as other faiths recognized in Indonesia (Jaelani et al., 2020). Thus an invention filed with the DJKI has the opportunity to be granted patent protection even though the invention concerned has been proven to have an element or content in the manufacturing process and its final product which is contrary to one of the religions in Indonesia or in this case the religion of Islam. The practice so far is that none of the inventions submitted to the DJKI that have been rejected as a result of an invention that contradicts religion in Indonesia is the most important thing is that the invention must fulfil the Patent granting requirements based on the provisions contained in the 2016 Patent Law (Aris et al., 2015).

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Conclusion

Based on the above discussion, it can be concluded that first, the background of the regulation regarding the provisions of an invention that is considered to be contrary to Religion in Indonesia as regulated in Article 9 letter a of the Law of the Republic of Indonesia Number 13 of 2016 is based on several justifications of Article 27.2 and Article. 27.3 TRIPs Agreement, justification based on the elaboration of the Pancasila as the ideology of the Indonesian people, especially the Precepts of the Almighty God and justification based on people's aspirations in the process of discussing the Draft Patent Law in 2001. Second, the provisions of an invention which is Considered Contrary to Islamic Religion in the pharmaceutical field which contains Unlawful elements cannot be implemented because the provisions of Article 9 letter a of the Law of the Republic of Indonesia Number 13 Year 2016 are universal meaning that Inventions that are contrary to religion cannot be implemented if there is only 1 (one) religion that considers an Invention to be contrary to the rules in question. In the future the determination of an invention that is considered to be contrary to religion in Indonesia needs to be synchronized between Law Number 13 Year 2016 concerning Patents and Law Number 33 Year 2016 concerning Halal Product Guarantee. Because the state is obliged to provide protection and guarantee regarding the halal products that are consumed and used by the public. Assurance regarding Halal Products should be carried out in accordance with the principles of protection, fairness, legal certainty, accountability and transparency, effectiveness and efficiency, and professionalism.

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