THE PHARMACEUTICAL PATENT PROTECTION IMPACT ON INDONESIA DRUGS PRICE*

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Abstract

This paper examines the pharmaceutical patent protection impact on Indonesian drugs price. As patent owner, companies could set high price for their drugs. However, such condition limits the access of the poor from patented drugs. Therefore, balance between patent protection, public welfare, and compliance to TRIPs agreement must be ensured.

Abstrak

Penelitian ini membahas dampak paten produk-produk farmasi terhadap harga obat di Indonesia. Sebagai pemegang hak paten, perusahaan farmasi dapat menetapkan harga yang tinggi. Namun, kondisi ini membatasi akses masyarakat miskin untuk memperoleh obat yang terpatenkan. Dengan demikian, harus ada keseimbangan antara perlindungan hak paten, kesejahteraan masyarakat, dan kepatuhan terhadap TRIPs.

Keywords*: pharmaceutical, patent protection, patented drug*s.

A. Introduction

In the post TRIPS era, patent protection for medicines has been a concern amongst WTO members because TRIPS requires members to provide patent protection for processes and products relating to pharmaceuticals.[1]These include protection for pharmaceutical compositions, therapeutic uses, polymorphs, active ingredients related forms and pharmaceutical processes.[2]

Many developing countries have objected to the inclusion of patent protection for pharmaceuticals within the WTO framework for three primary reasons. First, some developing countries believe that access to medicines is a human right.[3] They

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1 The legal foundation of this obligation is from article 27 of TRIPS which states "… patent shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application".

2 Carlos Correa, 2000, *Integrating Public Health Concern into Patent Legislation in Developing Countries*, p. 37.

3 See WHO Essential Drug and Medicines Policy, 2001, *Network For Monitoring The Impact Of Globalitation and Trips on Acces To Medicines*, p. 20.

worry that protection will restrict access to essential medicines.[4] Second, some view protection for pharmaceutical patents as unfair. Some developing countries noted that many developed countries refused to protect intellectual property rights sufficiently when protection was not in their best economic interests – such as when Netherlands did not provide patent protection during the 19th century.[5] Third, it is often argued that protection will hamper the development of local pharmaceutical companies in developing countries upon which increasing access to medicines.[6] These concerns are understandable because a number of studies have shown that patent protection for pharmaceuticals increases the price of drugs in developing countries.[7] Higher prices limit the access of the public, particularly the poor, to cheaper drugs.[8] Reduced access to important medicines has caused much conflict in many developing countries, including Indonesia.

For the Indonesian government, protection for pharmaceutical patents[9] constitutes a serious public health issue. It must balance its policy of protecting pharmaceutical patents[10] according to the TRIPS Agreement (international standards) and its goal of providing cheaper drugs (domestic developmental policy).[11] Unless the government provides sufficient protection for phar-

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4 See David P. Fidler, 2000, *International Law and Public Health Materials on and Analysis of Global Health Jurisprudence*, p. 259. See William Cornish, 2004, *Intellectual Property Omnipresent, Distracting, Irrelevant,* p. 11. According to the WHO estimation "one third of the world's population lacks access to the most basic medicines, while in the poorest parts of Africa and Asia this figure climbs to one half". Graham Dukes, 2006, *the Law and Ethics of Pharmaceutical Industry*, p. 263.

5 See Marco CEJ Bronckers, 1994, *The Impact of Trips: Intellectual Property Protection in Developing Countries*, 31 Common Mkt.L.Rev 1247. Julio Nogues, 1990, *Patents and pharmaceutical Drugs: understanding the Pressures on Developing Countries*, p. 24 (6) J. World Trade 82.

6 India has a strong opinion about the impact of pharmaceutical patent protection, particularly pharmaceutical product patents. This opinion can be found in the objectives of the Indian Patent Law of 1970 which abolished pharmaceutical product in that law for the purpose of developing "an independent Indian Pharmaceutical industry". See Carsten Fink, "How Stronger Patent Protection in India Might Affect the Behavior of Transnational Pharmaceutical Industries", at p. 7, available at *http://wbln0018.worldbank.org/research/workpapers.nsf/0/5d9b67dfa0777405852568e80065f3c4/$FILE/wps2352.pdf*. Another example is Brazil, which abolished the protection of pharmaceutical products in 1969 for the purpose of creating a stronger domestic pharmaceutical industry. Srividhya Ragavan (1), 2003, *Can't We All Get Along? The Case for a Workable Patent Model*, 35 Ariz. ST. L.J. 117, p. 7. See also Keith E. Maskus and Denise Eby Konan, 1994, *Trade- Related Intellectual Property Rights: Issues and Exploratory Results,* in *Analytical and Negotiating Issues in the Global Trading System*, Alan V. Deardorff and Robert M. Stern eds., p. 402-403.

7 For examples: Nogues (1990, 1993), Challu (1991), Chambouleyron (1995), Watal (1996, unpublished). See United Nations Conference on Trade and Development, 1996, *The Trips Agreement and Developing Countries*, p. 62. See K. Bala and Kiran Sagoo, "Patents and Prices", at *http://www.haiweb.org/pubs/hainews/patents%20and%20Prices.html,* April/May 2000.

8 See Theresa Beeby Lewis, 1996, "Patent Protection for the Pharmaceutical Industries: A Survey of the Patent Laws of Various Countries", 30 Int'l Law, p. 835.

9 Pharmaceutical patents cover both products and processes. However, this dissertation focuses more on pharmaceutical products. Graham Dukes defines pharmaceutical products as "a substance or a complex of substances which is administered to man or to animals in order to prevent, diagnose, alleviate or cure a disease, to relieve a symptom, or to modify bodily function in some way". Graham Dukes, supra note 4, at 3. For the purpose of this paper, the discussion about pharmaceutical products is limited to a substance which is administered to human beings.

10 Pharmaceutical patents (both process and product patents) were given limited protection in Indonesia for the first time under the Indonesian Patent Act of 1989.

maceutical patents, it faces sanctions from the WTO for violating the principles of international trade.

On the other hand, Indonesians' need to reduce the cost of medicines is pressing for four reasons. First, government budget for medications is limited.[12] Second, the rate of generic drugs sale is low.[13] Third, the burden of chronic diseases and emerging problems, such as HIV/AIDS is increasing at alarming levels.[14] Fourth the price of drugs due to pharmaceutical patent protection has increased.[15] This situation was caused in the past by the Indonesian government's failure to maximize a number of safeguards included within the TRIPS Agreement. This is attributable to government inaction and the unclear and flexible nature of those safeguards.[16]

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11 The tension is more evident after the Indonesian government complied with the TRIPS Agreement in 1997.

12 Indonesia's public health expenditure on health (0,6% of GDP or US$7,6 per capita annual) is significantly less than other ASEAN countries such as Thailand (1.9 % of GDP or US$35.5 per capita annual) and Philippines (1,6% of GDP or US$16,4 per capita annual). BPS-Statistic, Bappenas and UNDP Indonesia, "The Economics of Democracy: Financing Human Development in Indonesia", at *http://www.undp.or.id/pubs/ihdr2004_full.pdf*. The estimated data for Indonesia is from 1996-1997 and for Malaysia and Thailand is between 1995 and 1999.

13 Furthermore, Indonesian sale of generic drugs, which would be an effective strategy of providing cheaper drugs to the public, is only 10% of drug sales. This is lower than other countries in Asia, such as Thailand (23%), Singapore (22%) and Taiwan (70%). Media Indonesia Online, "Tarif RS Tidak Standar, Askes Sulit Berkembang (Hospital Fees Are Not Standard; Health Insurance Cannot Grow)", at *http://mediaindo.i2.co.id/cetak/berita.asp?action=cetak&id=2003042923442560*, April 30th, 2003. Compared to developed countries, such as Germany, USA and Japan, generic drug sales in Indonesia are lower than those countries where the sales comprise more than 30 % of drug sales. Kompas Newspaper, "Dana Masyarakat Dihemat Rp. 1 Trilyun, Jika 30 Persen Dokter Gunakan Obat Generik (Public Funds Can be Saved Rp. 1 Trillion, If 30% of Indonesian Doctors Use Generic Drugs)", at *http://www.kompas.com/kompas-cetak/0105 /23/iptek/ dana10.htm*, May 23rd, 200).

14 Relating to HIV prevalence, there is a significant increase number, particularly in the regions of Kalimantan, Papua and Riau. UNAIDS and WHO, 2003, *AIDS Epidemic Update*, Switzerland, UNAIDS, p. 5, 20-21. Nowadays, it is predicted that 90.000 – 130.000 Indonesians are infected by HIV. UNDP, "Laporan Perkembangan Pencapaian Tujuan Pembangunan Millennium Indonesia/A Progress Report of How to Realize the Indonesian Millennium Development", at *http://www.undp.or.id/pubs/imdg2004 /BI/Indonesia MDG_BI_Goal6.pdf*. In Papua, HIV prevalence reached 17% in 2002. Even though this number is not as high as in Africa or other Asian countries, the government should anticipate the steady growth of HIV due to the fast spread of this disease. In the near future, it is not impossible that the growth will be a national epidemic. Similarly, from 1987 to 2002 the number of AIDS sufferers in Indonesia was also significantly increasing. Up to the end of September 2003, there were 1,239 reported AIDS cases in Indonesia.

15 See some studies done by researchers in developing countries (supra note 7).

16 Regarding the public health issues, the TRIPS agreement did provide the safeguards, such as bolar provision, parallel imports, compulsory license and government use for every member of the WTO to handle the impact of pharmaceutical patent on public health. But, the Indonesian government has not yet used those safeguards effectively in its national patent law. Even though those safeguards were included in patent law, those cannot be applied due to lack of detailed implementing regulations. Besides that, the government tries to act carefully in implementing the safeguard because the TRIPS Agreement consists of minimum standards only but not a uniform law. Through these minimum standards, the TRIPS Agreement allows its members to "have considerable room to develop their own patent". Consequently, each member of the WTO has a different patent law standard including how to interpret the safeguards and to what extent those safeguards applications are consistent with the TRIPS Agreement. In practice, the different interpretation of the TRIPS safeguards creates a conflict mainly between developed countries and developing countries which needs to be solved at the dispute settlement body of the WTO. If one country is proved to be applying the safeguards inconsistently with the TRIPS Agreement, the country will face sanctions from the WTO for violating the principles of international trade. Not surprisingly, most developing countries hesitate to apply the safeguards on the ground of avoiding sanctions.

This paper examines the impact of pharmaceutical patent protection on the price of drugs in Indonesia. It focuses on two issues: (1) how does pharmaceutical patent protection affect drug prices in Indonesia? (2) Is patent law the only factor affecting drug prices in Indonesia?

B. Does Pharmaceutical Patent Protection Increase Drug Prices in Indonesia?

Attaran notes that only 1,4% of the WHO Essential Medicines List (EML) is patented so that the large majority of essential drugs should be accessible. He draws attention to poverty, lack of donor funding, and health system infrastructure as barriers to access.[17]

The International Federation of Pharmaceutical Manufacturers Association (IFPMA) makes a similar argument. This association states that patent protection affects only very small proportion of drugs in developing countries because over 95% of the WHO's list of essential drugs, those are most needed for treatment in developing countries, are non-patented drugs.[18] The protection of pharmaceutical products, therefore, does not impact the drug prices listed in the WHO's essential medicines.[19]

A large majority of articles disagree and argue that patent laws create barriers to access to affordable drugs. These studies show that pharmaceutical patent protection increases the price of drugs in developing countries.[20] Since the literature shows a debate about patents and prices, with the majority indicating patents are associated with higher prices, Attaran's paper and the research pharmaceutical companies' opinion challenge us to ask: what essential drugs are affected by patents?

In Indonesia only 55% of Essential Medicines List or DOEN are generic drugs. Therefore, an analysis of the relation between pharmaceutical patent and the price of drugs is relevant for Indonesia and other countries where patented drugs constitute a significant market share. There are three factors influencing the impact of patented drugs in Indonesia; a) government's limited ability to finance all of the generic drugs listed in DOEN b) low generic drug prescribing pattern and c) a weak commitment by local authorities in prescribing generic drugs under health decentralization. These factors are discussed below:

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17 Amir Attaran, "How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?" *Health Affairs*, *Volume 23, Number 3*, at p. 155, available at *http://content.health affairs.org/cgi/reprint/23/3/155*, March 21st, 2006. See also Harvey E. Bale, Jr., "Patents and Public Health: a Good and Bad Mix?", at p. 1, available at *http://www.cnehealth.org/pubs/bale_patents_and_public_health.htm*. Owen Lippert, "Poverty, Not Patents, is the Problem in Africa", at p. 1, available at *http://www.cnehealth.org/pubs/lippert_poverty_not_patents.htm*.

18 IFPMA (I), 1998, *the Question of Patents the Key to Medical Progress and Industrial Development*, p. 10.

19 *ibid.*

20 For examples: Nogues (1990, 1993), Challu (1991), Chambouleyron (1995), Watal (1996, unpublished). See United Nations Conference on Trade and Development, supra note 7, at p. 62; and K. Bala and Kiran Sagoo, 1999, supra note 7, at p.1.

1. Government's Limited Ability in Producing Generic Drugs Listed in DOEN

Since DOEN was implemented in Indonesia in 1980, the Indonesian government has not been able to provide 100% of generic drugs listed in DOEN to its people. In 2005, 220 generic drugs (55%) are listed among 400 essential drugs of DOEN.[21] The Decree of the Indonesian Health Minister No. 12/ MENKES/SK/I/2005 on the Price of Generic Drugs directs that 153 of the generic drugs (70%) listed in DOEN must be available in basic and public health facilities in Indonesia. The rest are excluded because the Indonesian government has limited financial ability for purchasing all the generic drugs listed in DOEN.[22] These "essential" generic drugs are appropriate, given the majority of disease problems confronted in public facilities, staff qualifications, and available equipment. For example, most generic drugs in DOEN are for tropical diseases, such as diarrhea, dengue fever, malaria, tuberculosis. Meanwhile the number of generic drugs for non-tropical diseases, such as high cholesterol, high blood pressures and cancer is very limited. Only one of the 19 drugs listed in DOEN for Sitotoxic (cancer) is included among the 153 essential generic drugs.[23] Attaran's argument that pharmaceutical patent does not affect overall drug expenditure since 96% of the WHO essential drug list are generics is not applicable to Indonesia. This is because only half of Indonesia's DOEN list is comprised of generic drugs.

Furthermore, the government's limited ability in providing all generic medicines listed in DOEN may increase the use of patented drugs making them still relevant to increased prices in Indonesia.

2. Low Percentage of Generic Drug Prescription in Certain Areas

In 2003, number of drug prescriptions by province in Indonesia was 28.389.959. This total included 20,810,557 prescriptions of generic drugs or 73,30%.[24] This data shows that in general a majority of drug prescriptions in Indonesia are dominated by generic drugs. It might seem that Attaran's argument is supported with this data. However, the discussion about pharmaceutical patent protection to access to essential medicines is still relevant. There are wide variations in drug prescribing patterns. First, using the same data above, it is evident that generic drug prescribing in some provinces is very low. Examples of this are East Kalimantan (26.53%), West Java (31.33%), West Kalimantan (38.42%), Yogyakarta (35.91%) and South East Sulawesi (47.32%).[25] One

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21 Depkes (The Ministry of Health), "Kebijakan Obat Nasional/KONAS (The National Drug Policy- draft)", available at *http://www.depkes.go.id/downloads/Konas.pdf*, at p. 6, September 23rd, 2005.

22 Interview with an anonymous respondent (a) on 2nd of May 2006 in Jakarta.

23 See Daftar Obat Essensial Nasional (DOEN) or the Indonesian Essential Medicines List 2002.

24 This data did not cover number and percentage of prescription of generic drugs in Banten, Bangka Belitung Islands, and South Kalimantan, Gorontalo, Maluku and Papua provinces. Result of Data Collection and Processing of Minimum Service Standard Performance Indicator in the Health Sector from 325 Districts/Municipals, 10/10/04 in Ministry of Health of Republic of Indonesia, 2003, *Indonesia Health Profile*, p. 175.

25 Result of Data Collection and Processing of Minimum Service Standard Performance Indicator in the health sector from 325 Districts/Municipals, 10/10/04 in Ministry of Health of Republic of Indonesia*, ibid.*

explanation is that populations which live in those areas have higher medicine expectations due to a lot of educated people (Bandung, the capital city of West Java and Yogyakarta are well known as student cities) and there are rapidly developing areas (East Kalimantan, West Kalimantan and South East Sulawesi).

Second, the use of generic drugs in basic health centers is high (73.30%) but lower in public hospitals. In a public hospital of a province in Indonesia, the use of generic drugs in 2004 was 3.358 (29%) and the use of non-generic drugs was 8.079 (71%). In 2005, the use of generic drugs was still lower where the number was 5.925 (14%) compared to non generic which was 35.102 (86%). [26]

This variation may be related to sicker patients at a hospital compared to a health center, since people may bypass a facility where they feel they cannot get effective care. Hospitals have other attributes that affect drug prescribing, including contacts with pharmaceutical representatives and a staff with more specialists.

According to data in 2004 collected from 4 state owned pharmacies in Yogya, it was found that total drug prescription was about 94.325. Among these, there were only 7.762 or 8,2% generic drug prescriptions of total drug prescription in 12 months.[27] These data show that the use of non-generic drugs in some provinces is dominant and that the relationship between pharmaceutical patents and the increase drug expenditures is still a relevant issue in Indonesia.

3. A Weak Commitment of Using Generic Drugs in Basic Health Centers and Public Health Facilities Under Health Decentralization

Before health decentralization (before 2002), the availability of generic drugs was 100% in PUSKESMAS (basic health centers). This is because central government procured and distributed generic drugs to basic health centers. If basic health centers need patented drugs, the government usually subsidizes the drug purchase.[28] However, after health decentralization, local governments expected that basic health centers and public health facilities would generate revenue through fees and drug purchases. Consequently, there is a tendency that under health decentralization basic health centers and public health facilities provide more non-generic drugs than before because of better revenues.[29] Survey in several hospitals in Central Kalimantan in April 2006 showed that drug prescribing pattern for respiratory infection (non pneumonia) was dominated by non-generic antibiotics that constituted 60%-90% of total drug prescriptions, raising costs.[30]

An optimal use of generic drugs has fallen under health decentralization. This is because the decision about drug purchasing

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26 This data was collected from field research in a province in Indonesia in June 2006.

27 This data was obtained from Depkes, 2005, *Data Profil Kesehatan Kota Yogyakarta Tahun 2005*, p. 81.

28 Interview with an anonymous respondent (b) on 26th of May 2006 in Jakarta.

29 Interview with an anonymous respondent (a), supra note 22.

30 Ayonni Rizal, "Penggunaan Obat Secara Rasional-Suatu Upaya Memberikan Pelayanan Kesehatan Optimal (2) (The Rational Use of Drug-2, An Effort to Provide an Optimal Health Service)", *Kalteng Pos*, at 6, July 1st, 2006.

is influenced by their weak commitments to the health sector.[31] This situation could worsen if pharmaceutical companies use their aggressive promotion to sell patented drugs to health providers. This expanded use of patent drugs in health centers and public health facilities make pharmaceutical patent protection more significant for the price of drugs in Indonesia.

C. The Impact of Pharmaceutical Patent Protection on Drug Prices in Indonesia

An exclusive right owned by patent holders significantly influences the price of drugs in Indonesia. Price control is an important factor. In Indonesia some branded generic drugs, outside the government price control, are almost as expensive as the patented drug making them unaffordable for many. An example is the price of Ketamin Injection which is 511% of international price references.[32] These finding accords to the drug price compared to patent drug price which is performed by all pharmaceutical companies in Indonesia as shown by table 1. All types of drugs in Indonesia have a different price factor.

Table 1
Price Factor of Several Types of Drugs in Indonesia

No.	Types of Drugs	Price Factor
1.	Patented Drugs	100 %
2.	Original Off-Patent	100% (the same as patented drug price)
3.	Branded Generic	40-80 % (of patented drug price)
4.	Low-Priced Branded Generic	30 % (of patented drug price)
5.	Obat Generik Berlogo	10-30% (of patented drug price)
6.	Obat Essential (DOEN)/PKD	10-25 % (of patented drug price)

Source: GP Farmasi Indonesia or the Indonesian Pharmaceutical Association, 2006, *Pengantar Pemahaman Komoditi Obat (the Introduction to Commodity Drugs),* Jakarta, at p. 3.

There are several possibilities that can explain the high price of generic drugs, particularly branded generic drugs in Indonesia. One is the absence of competition in the market. Frank and Salkever (1997), well-known economists concluded that competition among generic producers is important to lower the price of generic drugs.[33] Another interesting issue from table 3-3 is that the price of an original off-patent, which lost patent protection, can be as expensive as patent drugs in Indonesia. Frank and Salkever (1992 and 1997) found that the price of branded patented drugs may not lower after patent expiration.[34] Grabowski and Vernon (1992) explained

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31 Interview with an anonymous respondent (b), supra note 28.

32 Depkes, "Hasil Lokakarya Harga Obat di Indonesia: Kenyataan, Isu Hangat dan Agenda Reformasi (The Result of Seminar on Drug Prices in Indonesia: Reality, Current Issues and Reform Agenda)", Jakarta, June 29th, 2005, at p. 1, available at *http://www.litbang.depkes.go.id/update/Hsl_LHO.pdf*, May 4th, 2006.

33 Richard G. Frank and David S. Salkever, 1997, *Generic Entry and the Pricing of Pharmaceuticals*, (6) 1 J. Econ & Mgmt. Strategy, p. 89.

34 *ibid.* See also Ernst R. Berndt et. al., "The Long Shadow of Patent Expiration: Generic Entry and RX to OTC Switches", at p. 25, available at *http://www.duke.edu/~mkyle/RX%20to%20OTC%20paper.pdf*, November 8th, 2006. See F.M. Scherer, 1993, *Pricing, Profits, and Technological Progress in the Pharmaceutical Industry*, 7(3) J. Econ. Persp., p. 101.

that the price of off-patent drugs is still high if market demand persists. For example, after patent expiration due to brand loyalty among physicians who prescribe those drugs to their patients.[35] Furthermore, if originator companies claim new use patent based on clinical data test of off-patent drugs and use data exclusivity on it, they will retain the clinical data test from generic drug producers. Consequently, this will inhibit generic entry (this is discussed in detail on subchapter 2).[36]

The correlation between pharmaceutical patent and the increased price of drug is related to the fact that exclusive rights create a monopoly to patent holders (e.g. multinational pharmaceutical companies).[37] According to pharmaceutical companies the market price must cover production and marketing expenditures, plus a profit for shareholders. Patent protection is an important means for recouping the capital used for drugs production.[38] From patented drug producers' perspective, there should be a difference between the price of generic and patented drugs. International Federation of Pharmaceutical Manufacturers Associations (IFPMA) argues that getting a new drug from the laboratory to the patient takes time and is costly.[39] For examples, pharmaceutical companies may need 12 years and an average expenditure of $500 million before a pharmaceutical invention reaches the market.[40] The pharmaceutical business has economic risks because only "one of every 5000 new chemical entities discovered makes it to the market as a new drug."[41] However, many scholars argue that pharmaceutical companies take the excessive profits from an exclusive right given by the patent system.[42]

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35 Henry G. Grabowski and John Vernon (1), 1992, *Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act*, 35 (2) J. L. & Econ., p. 332-333 and 347. See F.M. Scherer, *ibid.* See also Mark A. Hurwitz and Richard Caves, 1988, *Persuasion or Information? Promotion and the Shares of Brand Name and Generic Pharmaceuticals*, 31 (2) J. L. & Econ, p. 305.

36 See Henry G. Grabowski and John Vernon (1), *ibid.* See also Henry G. Grabowski and John Vernon (2), 1986, *longer Patents for Lower Imitation Barriers: The 1984 Drug Act*, 76 Am. Econ. Rev., p. 195.

37 See John Braithwaite, 1984, *Corporate Crime in the Pharmaceutical Industry*, p. 163-166.

38 IFPMA (I), supra note 18, at 9; Rebecca S. Eisenberg (1), 2003, *Patents, Product Exclusivity and Information Dissemination: How Law Directs Biopharmaceutical Research and Development*, 72 Fordham L.Rev. 477, p. 2. See Brian Inglis, 1965, *Drugs, Doctors, and Diseases*, p. 20. Henry Gabowski, July 2002, "Patents, Innovation, and Access to New Pharmaceuticals", at. 4, available at *http://www.levine.sscnet.ucla.edu/archive/grabow-patents_innov.pdf*, September 22nd, 2006. See also Jesse W. Markham, Paul Talalay ed., 1964, *Economic Incentives and Progress in the Drug Industry in Drugs in Our Society*, p. 163-167.

39 Rebecca S. Eisenberg (2), 2005, *the Problem of New Uses*, *5 Yale J. Health Pol'Y, L. & Ethics*, p. 717.

40 IFPMA (I), supra note 39, at p. 9. Z. John Lu and William S. Comanor, "Strategic Pricing of New Pharmaceuticals", at p. 1, available at *http://www.mitpressjournals.org/doi/pdf/10.1162/003465398557212?CookieSet=1*, November 8th, 2006. See F.M. Scherer, supra note 36, at p. 1. See William S. Comanor, 1986, *The Political Economy of the Pharmaceutical Industry*, *24 J. Econ. Liter*., p. 1.

41 See Theresa Beeby Lewis, 1996, "Patent Protection for the Pharmaceutical Industries: A Survey of the Patent Laws of Various Countries", *30 Int'l Law 835*, p. 4. See also Henry Gabowski, supra note 39, at p. 4. See also Rebecca S. Eisenberg (2), supra note 40, at p. 1. See F.M. Scherer, *ibid.* See also Alan M. Fisch, 1994, *Compulsory Licensing of Pharmaceutical Patents: An Unreasonable Solution to An Unfortunate Problem, 34 Jurimetrics J. 295*, p. 3.

42 See John Braithwaite, supra note 38, at p. 161-166. See also Milton Silverman, et. al., 1982, *Prescriptions for Death-The Drugging of the Third World*, p. 97-101. See Z. John Lu and William S. Comanor, supra note 41, at p. 1.

They believe that the absence of competition during the patent protection give huge profits to pharmaceutical companies.[43] The expensiveness of patent drugs derives from the promotion cost, advertising cost and incentives to physicians or pharmacists who assist them to promote their products. These promotional costs are passed on to consumers.[44]

In practice, the structure of drug price in Indonesia consists of several components, including raw material cost, manufacturing cost, marketing cost, distribution cost, taxation and discount to pharmacies (see table 2 below).

Table 2
The Price Components of Amoxicillin in Indonesia

No	Price components of Amoxicillin	Percentages
1.	Raw Material Cost	5%
2.	Manufacture Cost	9%
3.	Marketing	50-80%
4.	Distribution Cost	6-15%
5.	Taxation	10%
6.	Net price rate at pharmacy	100%
7.	Price rate for consumers	135%

Source: Martuti Budiharto, et. al., 2004, at 25.

Table 2 shows marketing budget of Amoxicillin is the biggest component of drug price (50-80%). This is because pharmaceutical industries set a large budget for marketing their products toward physicians (drug promotion) and consumers (drug advertising).[45] The pharmaceutical industry expenditure for marketing may exceed that for research and development.[46] Another interesting fact is the different price between net pharmacies rate and consumer rate. In Indonesia, the price of drug controlled by the government is divided into two prices; net pharmacy price and the highest retail price.[47] Pharmacies have two sources of profits: from discount provided

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43 Michael Kremer and Rachel Glennerster, 2004, *Strong Medicine-Creating Incentives For Pharmaceutical Research on Neglected Diseases*, p. 33. John Braithwaite, *ibid,* at p. 161-166.

44 Harian Suara Indonesia Baru, "Kolusi antara Produsen Obat Dengan Oknum Dokter dan Rumah Sakit (The Collusion between Drug Producers, Physicians and Hospitals)", August 23rd, 2006, at p. 1, available at *http://www.hariansib.com/index2.php?option=com_content&task=view&id=11*, September 24th, 2006. Suara Pembaruan Daily, "Perkembangan Obat Generik Lamban (The Development of Generic Drugs is Slow)", May 6th, 2004, at p. 1, available at *http://www.suarapembaruan.com/ News/2004/05/06/ Kesra/kes03.htm*, September 20th, 2006.

45 Puneet Manchanda and Elizabeth Honka, 2005, *The Effects and Role of Direct – To – Physicians Marketing in the Pharmaceutical Industry: An Integrative Review,* 5 Yale J. Health Pol'y L. & Ethics 785, p. 1. See R.B. Smith, 1985, *The Development Of A Medicine*, p. 99.

46 Puneet Manchanda and Elizabeth Honka, *ibid*. See William Comanor, supra note 106, at p. 1196. See also Jay P. Bae, 1997, "Research on Pharmaceutical Drug Development, Use, and outcomes: Drug Patent Expirations and the Speed of Generic Entry", 32 (1) Health Services Research, p. 88, available at *http://www.pubmedcentral.nih/gov/picrender.fcgi?artid=1070171&blobtype=pdf*, November 8th, 2006).

47 Suara Pembaruan Daily, supra note 45.

by pharmaceutical companies at net price and from the consumers (35%) at the highest retail price. This practice has been criticized as excessive profits gained by unreasonable costs for consumers.[48]

These results show a relationship between pharmaceutical patent protection and a higher drug prices compared to those available for multisource drugs. These findings, that the protection of pharmaceutical patents affected the price of drugs before and after the TRIPS Agreement, concur with other studies. For example, in 1990 Nogues argued that patent protection for pharmaceutical drugs favours the pharmaceutical industry. He also concluded that pharmaceutical patents increase the price of drugs in developing countries. However, competition between brand names and the generic drug producers can minimize this impact if the generic drugs are promoted as effective and are acceptable to consumers.[49] In 1993, Nogues concluded that the introduction of pharmaceutical patent "would entail significant welfare losses and income gains to patent owners."[50]

In 1991, Challu found similar results in Argentina. After analyzing the Argentine pharmaceutical markets, Challu stated that patent protection resulted in "a 273 per cent price increase and a 45,4 per cent decrease in quantity demanded."[51] In 1994, Kim *et al* found that Intellectual Property Rights (IPR) policy change in the Republic of Korea affected pharmaceutical firm market. Pharmaceutical companies with more technological capability will gain benefit while those with less technological capacity experienced loss of their market.[52]

In the post TRIPS period, Subramanian conducted research on the likely impact of pharmaceutical patent products in small and large countries in 1995. He concluded that "either a perfectly competitive market or Nash-Cournot duopolistic market becomes a monopoly under patents."[53]

In the same year, Subramanian applied this research in five countries to India, Indonesia, Pakistan, the Philippines and Thailand. He found that annual price, welfare and profit effects were negative in all five of the countries (drug prices and profits rose, while fewer consumers could afford to pay).[54]

In 1995, Chambouleyron concluded that there were "significant price increases"

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48 *ibid.*

49 Julio Nogues, "Patents and Pharmaceutical Drugs: Understanding the Pressures on Developing Countries", 1990, *24 (6) J.World Trade*, p. 81-104.

50 Julio Nogues, 1993, *Social Costs and Benefits of Introducing Patent Protection for Pharmaceutical Drugs in Developing Countries*, 31 (1) Dev.Econ, p. 24-53. See UNCTAD, supra note 20, at p. 62.

51 Pablo Challu, 1991, *The Consequences of Pharmaceutical Product Patenting,* 15 (2) World Competition, p. 110. However, this study was criticized by Rozek because it is "fatally flawed in its conceptual and empirical analyses". See Richard P. Rozek, 1993, *the Consequences of Pharmaceutical Product Patenting: A Critique*, 16 (3) World Competition L. & Econ Rev., p. 91. UNCTAD, *ibid.*

52 Kim, Sang-Gon, Kong-Kyun Ro and Pyung-Il Yu, 1994, *Intellectual Property Protection Policy and Technology Capability*, 21 (2) SCI. & Pub. Pol'y, p. 121-130. UNCTAD, *ibid*.

53 A. Subramanian, "Trade-Related Intellectual Property Rights and Asian Developing Countries: An Analytical View", *Paper presented at the Conference on Emerging Global Trading Environment and Developing Asia, Manila, Philippines*, May 29-30. UNCTAD, *ibid*.

54 A. Subramanian, 1995, *Putting Some Numbers on the TRIPS Pharmaceutical Debate*, 10 (2-3) Int'l.J Techt. Mgmt., p. 252-268; UNCTAD, *ibid*, at p. 62.

and a fall of consumption in Argentina due to monopoly.[55] Watal in 1996 reported a similar result in India, in which the introduction of product patents in pharmaceuticals would increase 52 per cent and welfare losses to about US$ 33 million.[56] In mid-1999, K. Balla and Kiran Sagoo reported a survey conducted by Consumers International and Health Action International (CI/HAI) on the likely impact of patent on the retail prices of 16 drugs in 36 countries (ten developed countries, 25 developing countries, including Indonesia and one Commonwealth of Independent States/CIS). This survey concluded that there was a significant impact of pharmaceutical patent protection on the retail price of drugs in those countries and that the introduction of generic drugs could lower the price of originator's drug.[57]

D. Relevant Factors outside Pharmaceutical Patent Protection Which Affect the Increase Price of Drugs in Indonesia

This paper found that pharmaceutical patent protection is not the only factor affecting drug prices.[58] High price of drugs in Indonesia is influenced by pharmaceutical policy that results in weak control of drug distribution and an absence of price controls. Local pharmaceutical companies depend upon raw materials from abroad may encounter problems and health insurance organizations have failed to use volume purchases to negotiate the price of drugs.

Non-patent drug factors may also raise the price of generic drugs. In 1997 and 1998 a shortage of imported raw materials was associated with higher generic drug prices. The Department of Health reported that the highest price of generic drugs in Indonesia was in January 1998. It amounted 112,9%. Fluctuating international monetary exchange is another factor. In February 1998 and in March 1998, the generic drugs price increased about 50% and continued to rise to 63,19% in June 1998.[59] The increase of the prices was caused by economic crisis which appeared at the end of 1997 where the Indonesian currency (rupiah) to US$ 1 was depreciated from Rp.2000 to Rp.5000. In June 1998, there was the highest depreciation of the Indonesian currency to US dollar which reached almost Rp.15.000 per US dollar.[60]

Another factor related to price is a large number of pharmaceutical companies and pharmaceutical distributors. Pharmaceutical companies are only 198 but the number of pharmaceutical distributors is about 2.645.

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55 Andres Chambouleyron, 1995, *La Nueva Ley de Patentes Y Su Efecto Sobre Los Precios de Los Medicamentos. Analisis Y Propuestas (The New Law of Patents and Their Effects on the Prices of Medicines. Analysis and Answer)*, 18 (75) Estudios, p. 156-168. UNCTAD, *ibid*, p. 62.

56 Jayashree Watal, 1996, *Introducing Product Patents in the Indian Pharmaceutical Sector-Implications for Prices and Welfare*, 20 (2) World Competition L. & Econ.Rev. p. 19-20. UNCTAD, 1996, *ibid.*

57 K. Bala and Kiran Sagoo, supra note 20, at p. 1-4.

58 See also Carlos Correa, supra note 16, at p. 2.

59 Pusat Data Kesehatan DepKes RI (the Centre for Health Data of the Department of Health), 2000, Tinjauan tentang Perubahan Harga Obat Generik Sebelum Krisis Sampai Dengan Sekarang (The Overview Of The Change Of Generic Drug Prices Before Economic Crisis To Present), p. 11.

60 *ibid*, at p. 19.

This unbalance proportion cannot help the distributors to reach an efficient scale which brings about the increased distribution fee in Indonesia.[61] The limited opportunities to reach profit margin from small number of pharmaceutical companies as drug producers encourage the distributors to mark up the distribution fee in Indonesia. This fee will be the profit for them. Then, the increased distribution fee increases the drug prices.

E. Conclusion

Patent law is not the only factor increasing the price of drugs in Indonesia. This paper acknowledges the importance of additional factors (e.g. public health policy, drug pricing, distribution system, and surveillance of prescribing patterns) besides patent law that affects access to medicines. Although these factors are outside the scope of this paper, they illustrate the need to involve a multi-sectoral group of policymakers and stakeholders to improve access to medicines in Indonesia.

Therefore, Indonesia should seek a balance between pharmaceutical patent protection and use of policies and strategies that are essential for its public welfare. It must also assess a set of non-patent issues affecting the use of available drugs, particularly generic drugs.

Finally, Indonesia will need to tailor its approach to local needs and opportunities. Variations in economic level, national goal, legislative experience, and pharmaceutical industry development will influence policy options and priorities.

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[61] Gatra Magazine, "Orang Sakit Dilarang Miskin (Sick People Are Not Allowed to Be Poor)", Gatra No. 34 year XII, July 12nd, 2006, at p. 82.

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