PENERAPAN KLAUSUL FLEKSIBILITAS *TRIPs AGREEMENT* DALAM PASAL 20 UNDANG-UNDANG NOMOR 13 TAHUN 2016 TENTANG PATEN TERHADAP IMPORTASI VAKSIN COVID-19

SKRIPSI

Oleh:

MOCH. IRFAN DWI SYAHRONI
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BAGIAN HUKUM PERDATA
FAKULTAS HUKUM
UNIVERSITAS JEMBER
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SKRIPSI

Diajukan guna melengkapi tugas akhir dan memenuhi salah satu syarat
untuk menyelesaikan Program Studi Ilmu Hukum (S1)
dan mencapai gelar Sarjana Hukum

Oleh:

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2021

MOTTO

‘‘*Kebijaksanaan seorang pembuat hukum tidak hanya terdiri dari landasan keadilan, tetapi juga penerapannya; mempertimbangkan dengan cara apa hukum mendapat kepastian*.”

– John Locke –[1]

[1] John Locke, Macpherson, *Crawford Brough, Second Treatise of Government*, Hackett Publishing Company, Indianapolis, 1980.

[2] Winner Sitorus, “Kepentingan Umum dalam Perlindungan Paten”, *Jurnal Yuridika*, Vol. 29 No. 1, 2014, h. 41.

[3] Pasal 20 Undang-Undang Nomor 13 Tahun 2016 tentang Paten, di mana ayat (1) menyatakan bahwa pemegang paten wajib membuat produk atau menggunakan proses di Indonesia serta

PERSEMBAHAN

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Jember, 15 Januari 2021

Penulis

PERNYATAAN

Saya yang bertanda tangan di bawah ini:

Nama : Moch. Irfan Dwi Syahroni

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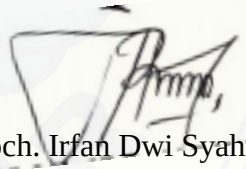
menyatakan dengan sesungguhnya bahwa karya ilmiah yang berjudul: **"PENERAPAN KLAUSUL FLEKSIBILITAS *TRIPs AGREEMENT* DALAM PASAL 20 UNDANG-UNDANG NOMOR 13 TAHUN 2016 TENTANG PATEN TERHADAP IMPORTASI VAKSIN COVID-19"** adalah benar-benar hasil karya sendiri, kecuali jika dalam pengutipan substansi disebutkan sumbernya dan belum pernah diajukan pada institusi manapun, serta bukan karya jiplakan. Saya bertanggung jawab atas keabsahan dan kebenaran isinya sesuai dengan skripsi ilmiah yang harus dijunjung tinggi.

Demikian pernyataan ini saya buat dengan sebenar-benarnya, tanpa adanya tekanan dan paksaan dari pihak manapun serta bersedia mendapat sanksi akademik jika ternyata dikemudian hari pernyataan ini tidak benar.

Jember, 15 Januari 2021

Yang menyatakan,



Moch. Irfan Dwi Syahroni

170710101357

PENGESAHAN

Skripsi berjudul **"Penerapan Klausul Fleksibilitas *TRIPs Agreement* dalam Pasal 20 Undang-Undang Nomor 13 Tahun 2016 tentang Paten Terhadap Importasi Vaksin Covid-19"** karya Moch. Irfan Dwi Syahroni telah diuji dan disahkan pada:

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RINGKASAN

Penerapan Klausul Fleksibilitas *TRIPs Agreement* dalam Pasal 20 Undang-Undang Nomor 13 Tahun 2016 tentang Paten Terhadap Importasi Vaksin Covid-19; Moch. Irfan Dwi Syahroni, 170710101357; 2021: 57 halaman; Program Studi Ilmu Hukum Fakultas Hukum Universitas Jember.

Di tengah pandemi *Corona Virus Disease 2019* (Covid-19), banyak negara-negara berlomba untuk menemukan vaksin Covid-19. Beberapa vaksin yang telah dibuat, yaitu Sinovac (China), Pfizer (Amerika Serikat) hingga AstraZeneca (Inggris). Meskipun, saat ini pemerintah telah mempersiapkan Vaksin Merah Putih, namun bahan bakunya tetap berasal dari luar negeri yaitu dari China. Pada dasarnya, produsen vaksin dalam negeri masih dihadapkan oleh persoalan keterbatasan terhadap hak paten. Sebagaimana diketahui bahwa Oleh karena itu, dengan menggunakan penelitian hukum normatif, penelitian ini menemukan beberapa permasalahan yang dihadapi oleh Indonesia dalam sistem patennya. Beberapa permasalahan tersebut yaitu berkaitan dengan pelaksanaan paten yang didasarkan atas Pasal 20 Undang-Undang Nomor 13 Tahun 2016 tentang Paten. Di mana dalam ketentuan tersebut tidak memuat aturan yang spesifik dan keluwesan mengenai skenario paten dalam perlindungan inventor asing khususnya. Pada akhirnya, tulisan ini menghasilkan 3 (tiga) alternatif. Pertama, dengan beberapa norma dalam ketentuan kewajiban pemegang paten untuk membuat produk dan menggunakan proses di Indonesia. Kedua, penerapan fleksibilitas *TRIPs Agreement* mampu meningkatkan posisi perdagangan dan investasi, mengembangkan inovasi dan mendorong iklim persaingan secara kompetitif. Ketiga, mengenai mekanisme pengadaan vaksin Covid-19 dapat dilakukan dengan memberikan paten terhadap metode ataupun platform vaksin yang boleh digunakan maupun dengan melaksanakan Perjanjian Kerjasama Paten.

SUMMARY

Application of the TRIPs Agreement Flexibility Clause in Article 20 of Law Number 13 of 2016 concerning Patents Against the Importation of Covid-19 Vaccines; Moch. Irfan Dwi Syahroni, 170710101357; 2021: 57 pages; Law Study Program, Faculty of Law, University of Jember.

In the midst of the Corona Virus Disease 2019 (Covid-19) pandemic, many countries are competing to find a Covid-19 vaccine. Several vaccines have been made, namely Sinovac (China), Pfizer (United States) to AstraZeneca (UK). Although, currently the government has prepared the Red and White Vaccine, the raw materials still come from abroad, namely from China. Basically, domestic vaccine producers are still faced with the problem of limitations on patent rights. As it is known, therefore, by using normative legal research, this research finds several problems faced by Indonesia in its patent system. Some of these problems are related to the implementation of patents based on Article 20 of Law Number 13 of 2016 concerning Patents. Where the provisions do not contain specific rules and flexibility regarding patent scenarios in the protection of foreign inventors in particular. In the end, this paper produces 3 (three) alternatives. First, with several norms in the provisions on the obligations of patent holders to make products and use processes in Indonesia. Second, the application of the flexibility of the TRIPs Agreement is able to improve trade and investment positions, develop innovation and promote a competitive climate. Third, regarding the mechanism for procuring the Covid-19 vaccine, it can be done by granting a patent for a vaccine method or platform that can be used or by implementing a Patent Cooperation Agreement.

DAFTAR ISI

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DAFTAR PERATURAN PERUNDANG-UNDANGAN

1. Peraturan Presiden Nomor 99 Tahun 2020 tentang Pengadaan Vaksin dan Pelaksanaan Vaksinasi dalam Rangka Penanggulangan Pandemi *Corona Virus Disease 2019* (Covid-19).
2. Undang-Undang Nomor 13 Tahun 2016 tentang Paten.

BAB 1
PENDAHULUAN

1.1 Latar Belakang

Di saat negara-negara lain, seperti Thailand, China hingga Rusia mendominasi guna menemukan dan mengklaim vaksin *Corona Virus Disease* (Covid-19). Produsen vaksin dalam negeri masih dihadapkan oleh persoalan keterbatasan terhadap hak paten.[2] Hal ini dikarenakan dalam ketentuan Pasal 20 Undang-Undang Nomor 13 Tahun 2016 tentang Paten (UU Paten) tidak memuat aturan yang spesifik dan keluwesan mengenai skenario paten dalam perlindungan terhadap kepentingan hukum dalam negeri.[3] Sedangkan, kalimat transfer teknologi dalam ketentuan tersebut hanyalah suatu slogan semata.[4] Hal ini dikarenakan tidak ada suatu mekanisme kontrol terhadap kewajiban transfer teknologi sehingga gagasan tersebut hanya berupa angan-angan yang tertuang dalam undang-undang.[5] Pasal 20 UU Paten menyatakan bahwa pemegang paten wajib membuat produk atau menggunakan proses di Indonesia.[6] Ketentuan tersebut dimaksudkan bagi setiap pemegang paten yang telah mengajukan permohonan dan mendapat perlindungan paten (*granted*) dari Indonesia, maka diharuskan untuk membuat produk atau menggunakan prosesnya di Indonesia.

Di samping itu, dalam pembuatan dan penggunaan paten tersebut juga harus menunjang berbagai aspek, diantaranya transfer teknologi, penyerapan investasi dan/atau penyediaan lapangan pekerjaan.[7] Bilamana ditinjau dari politik hukum,[8]

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2 Winner Sitorus, "Kepentingan Umum dalam Perlindungan Paten", *Jurnal Yuridika*, Vol. 29 No. 1, 2014, h. 41.

3 Pasal 20 Undang-Undang Nomor 13 Tahun 2016 tentang Paten, di mana ayat (1) menyatakan bahwa pemegang paten wajib membuat produk atau menggunakan proses di Indonesia serta ayat (2) menyatakan bahwa membuat produk atau menggunakan proses sebagaimana dimaksud pada ayat (1) harus menunjang transfer teknologi, penyerapan investasi dan/atau penyediaan lapangan kerja.

4 Agus Sardjono, *Membumikan HKI di Indonesia*, Nuansa Aulia, Bandung, 2009, h. 160.

5 Frederick Abbott, et. al., *The International Intellectual Property System: Commentary and Materials*, Kluwer Law International, The Hague, 1999, h. 8, fakta inilah yang dikatakan oleh Abbott sebagai tidak ada bukti bahwa rezim paten berpengaruh secara signifikan pada proses alih teknologi atau mendorong terjadinya pertumbuhan ekonomi negara-negara berkembang.

6 Pasal 20 ayat (1) Undang-Undang Nomor 13 Tahun 2016 tentang Paten.

7 Pasal 20 ayat (2) Undang-Undang Nomor 13 Tahun 2016 tentang Paten.

maka Pasal 20 UU Paten difokuskan bagi kemandirian dan kemajuan teknologi dalam negeri tanpa ada ketergantungan dengan pihak asing. Akan tetapi, ketentuan tersebut justru sarat akan persoalan dalam penerapannya. Beberapa persoalan yang muncul tersebut, diantaranya karena dianggap bertentangan dengan *Article 27 Agreement on Trade-Related Aspects of Intellectual Property Rights* (*TRIPs Agreement*).[9] Di tambah lagi dengan bagaimana kans para inventor dalam negeri jika invensi yang mereka daftarkan ke negara lain juga menerapkan aturan yang sama dengan Indonesia.[10]

Pelaksanaan paten sebagaimana ditegaskan dalam Pasal 20 UU Paten merupakan salah langkah bagi Indonesia dalam menunjang kemandirian dalam penguasaan teknologi. Akan tetapi, ketentuan dalam Pasal 20 UU Paten dinilai terlalu sulit untuk diimplementasikan. Hal ini dikarenakan, adanya kekakuan dan ketidakjelasan ketentuan dalam pasal tersebut, diantaranya tidak ditegaskan mengenai waktu dimulainya pelaksanaan paten oleh pemegang paten hingga macam cakupan bidang paten. Sehingga diperlukan pengaturan yang lebih tegas terhadap pelaksanaan paten di dalam ketentuan tersebut. Ketidakjelasan ketentuan tersebut menyebabkan tingkat permohonan paten baik dari inventor dalam negeri atau luar negeri mengalami penurunan. Pada tahun 2017, jumlah permohonan paten dari Amerika Serikat sebesar 1.672 aplikasi sedangkan pada tahun 2018 sebesar 1.033 aplikasi. Begitu juga, di Indonesia pada tahun 2017 jumlah permohonan paten sebesar 2.842 sedangkan pada tahun 2018 sebesar 1.720

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8 Moh Mahfud M. D, *Membangun Politik Hukum, Menegakkan Konstitusi*, Rajawali Pers, Jakarta, 2010, h. 15-16

9 *Article 27 Agreement on Trade-Related Aspects of Intellectual Property Rights state that Subject to the provisions of paragraphs 2 and 3, patents 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.5 Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.*

10 Muh. Ali Masnun dan Dina Roszana, "Persoalan Pengaturan Kewajiban Pemegang Paten untuk Membuat Produk atau Meggunakan Proses di Indonesia", *Jurnal Hukum Ius Quia Iustum*, Vol. 26, No. 2, Mei 2019, h. 328-329.

aplikasi. Sedangkan pada tahun 2019 baik itu permohonan dari dalam negeri maupun luar negeri tercatat nihil permohonan.[11]

Menyikapi hal tersebut, maka pemerintah harus mempertegas lagi ketentuan mengenai pembuatan, penggunaan dan perlindungan paten di Indonesia. Pasalnya paten diberikan oleh pemerintah kepada inventor atas invensinya untuk mencegah para inventor independen[12] menggunakan invensi tersebut selama jangka waktu perlindungnan paten masih berlaku. Terlebih invensi dalam bidang kesehatan, di mana ketika perusahaan-perusahaan farmasi hendak menjual obat-obatan ataupun alat kesehatan yang mereka diproduksi ke pasar global, maka mereka menyadari bahwa teknologi yang digunakan membutuhkan biaya riset yang begitu besar,[13] sehingga rentan adanya upaya peniruan.[14] Oleh karena itu, *TRIPs Agreement* hadir sebagai suatu bentuk perlindungan terhadap berbagai invensi, salah satunya dalam bidang kesehatan. Di mana dalam *TRIPs Agreement* mengharuskan adanya suatu perlindungan paten secara universal setiap invensi di bidang teknologi (*in all fields of technology*), termasuk di dalamnya adalah teknologi pengobatan (*pharmaceutical patent*)[15] dan bioteknologi.

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[11] DJKI, "Statistik Permohonan Paten Berdasarkan Negara Asal", Diakes dari https://statistik.dgip.go.id/statistik/production/paten_negara.php, pada Sabtu, 3 Oktober 2020.

[12] Cynthia Wagner Weick and Cynthia F. Eakin, "Independent Inventors and Innovation", *International Journal of Entrepreneurship and Innovation*, February 2005, h. 5, menyebutkan bahwa inventor independen atau *independent inventors* yaitu mereka yang hasil penemuannya lebih mengarah pada perangkat keras, produk rumah tangga/industri dan mainian dengan tujuan untuk dikomersialkan.

[13] Dea Melina Nugraheni, "Perlindungan Paten dan Fleksibilitas Persetujuan TRIPs di Bidang Farmasi di Indonesia", *Tesis*, Fakultas Hukum, Universitas Indonesia, Juli 2011, h. 11, dalam di mana menyebutkan bahwa perusahaan-perusahaan farmasi besar berpendapat bahwa perlindungan kekayaan intelektual diperlukan untuk mendapatkan penghasilan untuk mendanai kegiatan riset. Akan tetapi, berdasarkan laporan keuangan mereka pada tahun 2004 silam, sebanyak tujuh perusahaan farmasi terbesar di Amerika Serikat rata-rata hanya menghabiskan 14% dari pendapatan mereka untuk kegiatan riset sedangkan 32% dihabiskan untuk kegiatan pemasaran, periklanan dan administrasi. Mereka juga melaporkan keuntungan mereka, sebesar 18% dari pendapatan, adalah lebih besar dari biaya yang dikeluarkan untuk riset. Terlebih lagi, banyak penelitian yang dilakukan oleh industri farmasi adalah untuk membuat versi yang lebih mahal dari obat-obatan yang ada (obat- batan generik bermerek) atau untuk memperluas monopoli untuk pemanfaatan baru obat-obatan lama.

[14] Agus Sardjono, *Hak Kekayaan Intelektual dan Pengetahuan Tradisional*, Alumni, Bandung, 2010, h. 147-148.

[15] Frederick Abbott, et. al., *The International Intellectual Property System: Commentary and Materials*, Kluwer Law International, The Hague, 1999, h. 533-534, *Report of the Appelate Body* dari WTO dalam sengketa antara Amerika Serikat dengan India merekomendasikan bahwa India harus memberikan perlindungan kepada paten di bidang farmasi. Sengketa ini

Sebenarnya *TRIPs Agreement* memberikan beberapa fleksibilitas berupa lisensi wajib, *bolar provision*[16] dan impor paralel yang mana fleksibilitas-fleksibilitas tersebut ditujukan untuk melindungi kesehatan masyarakat[17] serta meningkatkan persaingan usaha. Fleksibilitas tersebut hanya dapat dijalankan bilamana Indonesia memasukkan ketentuan-ketentuan tersebut ke dalam undang-undang nasionalnya. Akan tetapi dalam praktiknya hingga saat ini beberapa klausul fleksbilitas tersebut belum pernah diterapkan oleh Indonesia[18] baik itu terhadap produk di bidang farmasi maupun produk di bidang lain.

Atas dasar latar belakang pemikiran tersebut, maka penulis berusaha untuk melakukan penelitian skripsi dengan judul:

"Penerapan Klausul Fleksibilitas *TRIPs Agreement* dalam Pasal 20 Undang-Undang Nomor 13 Tahun 2016 tentang Paten Terhadap Importasi Vaksin Covid-19"

1.2 Rumusan Masalah

Berangkat dari latar belakang tersebut, skripsi ini memfokuskan beberapa permasalahan, diantaranya:

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muncul dilatarbelakangi karena India dengan sengaja mengeluarkan industri farmasi dari sistem paten. Selain India, negara-negara lainnya yang juga tidak memberikan perlindungan sama sekali kepada paten di bidang farmasi adalah negara-negara Amerika Latin, seperti Colombia dan Chile. Kedua negara tersebut tidak memberikan perlindungan paten di bidang farmasi hingga tahun 1990. Lihat juga Emawati Junus, "Ketentuan TRIPs pada Pengaturan Paten di Bidang Farmasi di Indonesia", *Tesis Magister Hukum*, Universitas Diponegoro, Semarang, 2003, h. 4.

[16] Cita Citrawinda Priapantja, *Hak Kekayaan Intelektual: Tantangan Masa Depan*, Badan Penerbit Fakultas Hukum Universitas Indonesia, Jakarta, 2003, h. 48, adapun yang dimaksud dengan bolar provision yaitu adanya suatu pengecualian-pengecualian terhadap suatu hal dalam rangka memudahkan pemasaran obat-obatan generik.

[17] Soekidjo Notoatmodjo, *Ilmu Kesehatan Masyarakat: Prinsip-Prinsip Dasar*, Rineka Cipta, Jakarta 1997, h. 10, di mana terdapat suatu ilmu yang khusus mempelajari kesehatan masyarakat, yaitu ilmu kesehatan masyarakat. Definisi ilmu kesehatan masyarakat menurut Winslow adalah ilmu dan seni untuk mencegah penyakit, memperpanjang hidup dan meningkatkan kesehatan, melalui usaha-usaha pengorganisasian masyarakat untuk perbaikan sanitasi lingkungan, pemberantasan penyakit-penyakit menular, pendidikan untuk kebersihan perorangan, pengorganisasian pelayanan-pelayanan medis dan perawatan untuk diagnosis dini dan pengobatan, serta pengembangan rekayasa sosial untuk menjamin setiap orang terpenuhi kebutuhan hidupnya yang layak dalam memelihara kesehatannya.

[18] Dea Melina Nugraheni, op.cit, 13, h. 137, berdasarkan data tertulis yang diperoleh dari Bapak Budi Djanu Purwanto, Kepala Biro Hukum dan Hubungan Masyarakat BPOM, tertanggal 31 Mei 2011.

1. Apa *ratio legis* yang mengharuskan pemegang paten membuat produk dan menggunakan proses di Indonesia?
2. Apa akibat hukum atas penerapan klausul fleksibilitas *TRIPs Agreement* dalam Pasal 20 Undang-Undang Nomor 13 Tahun 2016 tentang Paten?
3. Bagaimanakah mekanisme pengadaan vaksin Covid-19 dengan menerapkan klausul fleksibilitas *TRIPs Agreement*?

1.3 Tujuan Penelitian

Adapun tujuan dari penulisan skripsi penulis kategorikan ke dalam tujuan umum dan tujuan khusu, diantaranya:

1.3.1 Tujuan Umum

1. Sebagai persyaratan guna meraih gelar Sarjana Hukum di Fakulta Hukum Universitas Jember
2. Sebagai salah satu bentuk pengaplikasian tridharma perguruan tinggi, yaitu penelitian guna memajukan sektor-sektor di dalam masyarakat
3. Besar harapan penulisan skripsi ini dapat memberikan kontribusi keilmuan kepada pembaca

1.3.2 Tujuan Khusus

1. Mengetahui dan memahami *ratio legis* yang mengharuskan pemegang paten membuat produk dan menggunakan proses di Indonesia.
2. Mengetahui dan memahami akibat hukum atas penerapan klausul fleksibilitas *TRIPs Agreement* dalam Pasal 20 Undang-Undang Nomor 13 Tahun 2016 tentang Paten bagi pemegang paten.
3. Mengetahui dan memahami mekanisme pengadaan vaksin Covid-19 dengan menerapkan klausul fleksibilitas *TRIPs Agreement* dalam Pasal 20 Undang-Undang Nomor 13 Tahun 2016 tentang Paten.

1.4 Manfaat Penelitian

Berdasarkan tujuan penelitian yang hendak dicapai, maka penelitian ini diharapkan mempunyai manfaat dalam pendidikan baik secara langsung maupun tidak langsung. Adapun manfaat penelitian ini adalah sebagai berikut :

1.4.1 Manfaat Teoritis

Manfaat secara teoritis atas hasil penelitian ini diharapkan dapat bermanfaat, diantaranya:

a. Memberikan pemahaman kepada mahasiswa pada khususnya dan masyarakat luas pada umumnya terkait perlindungan hak kekayaan intelektual di bidang paten;
b. Memberikan sumbangan pemikiran terkait kekayaan intelektual di bidang paten yang terus berkembang sesuai dengan perkembangan teknologi; dan
c. Sebagai referensi terhadap penelitian-penelitian selanjutnya yang berhubungan dengan perlindungan hak kekayaan intelektual di bidang paten serta menjadi bahan kajian lebih lanjut.

1.4.2 Manfaat Praktis

Sedangkan, manfaat secara praktis penelitian ini dapat bermanfaat sebagai berikut:

a. Sebagai landasan kerangka kerja bagi *stakeholders* agar mampu memfasilitasi perlindungan paten di Indonesia;
b. Agar dapat dijadikan referensi bagi mahasiswa dalam pengambangan terhadap penelitian hukum khususnya terkait perlindungan kekayaan intelektual di bidang paten; dan
c. Diharapkan penilitian ini dapat dijadikan referensi bagi peneliti lain yang akan mengangkat tema yang serupa dengan perspektif yang berbeda.

1.5 Metode Penelitian

Sunaryati Hartono menegaskan bahwa metode penelitian selalu mencari titik-titik tolak yang pasti tentang bagaimana suatu penelitian harus dilakukan secara analitis agar dapat menghasilkan kesimpulan yang dapat dipertanggungjawabkan.[19] Berdasarkan asan tersebut, dalam melakukan suatu penelitian hukum harus disusun secara sistematis serta berdasar atas fakta-fakta ilmiah. Oleh karena itu, dalam penulisan skripsi ini, penulis menggunakan metode sebagai berikut:

1.5.1 Tipe Penelitian

Penyusunan skripsi ini menggunakan tipe penelitian normatif,[20] di mana menempatkan hukum sebagai suatu sistem norma. Adapun yang dimaksud dengan sistem norma tersebut meliputi berbagai asas, norma serta kaidah dari peraturan perundang-undangan yang berlaku. Oleh karena itu, dengan menggunakan penelitian normatif, penulis melakukan analisis terhadap instrumen hukum nasional yaitu Undang-Undang Nomor 13 Tahun 2016 tentang Paten, instrumen hukum internasional yaitu *TRIPs Agreement* dan instrument hukum lainnya.

1.5.2 Pendekatan Penelitian

Banyak jenis pendekatan penelitian dalam ilmu hukum[21] yang dapat digunakan dalam menganalisis permasalahan yang akan dibahas. Namun, dalam penelitian ini hanya akan menggunakan dua pendekatan, yaitu pendekatan undang-undang (*Statute Approach*) dan pendekatan konseptual (*Conceptual Approach*).[22] Pertama, pendekatan undang-undang ditujukan

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[19] C.F.G. Sunaryati Hartono, *Penelitian Hukum di Indonesia pada Akhir Abad ke-20*, Penerbit Alumni, Bandung, 1994, h. 108.

[20] Peter Mahmud Marzuki, *Penelitian Hukum Edisi Revisi*, Kencana Prenada, Jakarta, 2015, h. 35, di mana dalam bukunya, yang dimaksud dengan penelitian hukum normatif yaitu suatu penelitian hukum yang meletakkan hukum sebagai sistem norma.

[21] Johan Nasution, *Metode Penelitian Ilmu Hukum*, Mandar Maju, Bandung, 2008, h. 96.

[22] Peter Mahmud Marzuki, op.cit, 20, h. 133-177, di mana dalam bukunya yang dimaksud dengan pendekatan undang-undang (*statute approach*) yaitu suatu pendekatan yang dapat dilakukan dengan cara menelaah berbagai peraturan perundang-undangan yang berlaku dengan isu hukum yang akan dibahas. Sedangkan, pendekatan konseptual (*conceptual approach*) yaitu suatu pendekatan yang dapat dilakukan dengan menggunakan berbagai konsep ilmu hukum di dalam literature terhadap isu hukum yang sedang dibahas.

guna dapat mengkaji terhadap kesesuaian antara satu undang-undang dengan undang-undang lainnya. Kedua, penggunaan pendekatan konseptual ini ditujukan guna mencari konsep-konsep yang berkaitan dengan permasalahan yang dibahas yaitu dengan mempelajari pandangan-pandangan serta doktrin-doktrin para ahli di bidang hukum hingga farmasi.

1.5.3 Sumber Bahan Hukum

Peter Mahmud Marzuki menyatakan bahwa dalam rangka memberikan solusi atas isu hukum yang sedang dibahas, maka diperlukan berbagai sumber penelitian. Dalam penelitian ini, penulis menggunakan tiga bahan hukum, diantaranya bahan hukum primer, bahan hukum sekunder dan bahan hukum tersier.

1.5.3.1 Bahan Hukum Primer

Bahan hukum ini dapat berupa peraturan perundang-undangan, catatan resmi dalam pembuatan peraturan perundang-undangan, putusan hakim[23] serta ketentuan peraturan perundang-undangan baik nasional maupun internasional yang telah memiliki kekuatan hukum mengikat. Adapun bahan hukum yang penulis gunakan dalam penelitian ini, diantaranya:

1. Undang-Undang Nomor 13 Tahun 2016 tentang Paten,
2. Undang-Undang Nomor 7 Tahun 2014 tentang Perdagangan,
3. Peraturan Menteri Hukum dan HAM Nomor 15 Tahun 2018 tentang Pelaksanaan Paten oleh Pemegang Paten,
4. Peraturan Menteri Kesehatan Nomor 1799/MENKES/PER/XII/2010 tentang Industri Farmasi,
5. Peraturan Presiden Nomor 99 Tahun 2020 tentang Pengadaan Vaksin dan Pelaksanaan Vaksinasi dalam Rangka Penanggulangan Pandemi *Corona Virus Disease 2019* (Covid-19), dan
6. *Agreement on Trade-Related Aspects of Intellectual Property Rights* (*TRIPs Agreement*).

[23] *Ibid*, h. 181.

1.5.3.2 Bahan Hukum Sekunder

Bahan hukum ini tidak mengikat, akan tetapi erat kaitannya dengan bahan hukum primer serta mendukung mengkaji terhadap isu hukum yang dibahas. Bahan hukum sekunder tersebut dapat berupa buku, jurnal hukum, artikel ilmiah dan karya ilmiah lainnya yang meneliti tentang fleksibilit *TRIPs Agreement* terhadap UU Paten dalam produksi vaksin.

1.5.3.3 Bahan Hukum Tersier

Bahan hukum tersier diartikan sebagai bahan hukum yang dapat mendukung dala, memberikan penjelasan terhadap bahan hukum primer dan sekunder. Adapun bahan hukum yang penulis gunakan dalam penelitian ini, diantaranya *Black's Law Dictionary*, Kamus Besar Bahasa Indonesia dan Kamus Hukum.

1.5.4 Metode Pengumpulan Bahan Hukum

Dalam penelitian ini, bahan hukum dikumpulkan melalui prosedur inventarisasi dan identifikasi peraturan perundang-undangan dan klasifikasi bahan hukum sesuai rumusan permasalahan. Oleh karena itu, teknik pengumpulan bahan hukum yang digunakan dalam penelitian ini adalah dengan studi kepustakaan. Studi kepustakaan dilakukan dengan beberapa tahapan, diantaranya membaca, menelaah, mencatat, membuat ulasan bahan-bahan pustaka hingga penulusuran melalui media internet yang ada kaitannya dengan isu hukum paten baik dalam lingkup nasional maupun internasional.

1.5.5 Analisa Bahan Hukum

Analisis terhadap bahan hukum, meliputi bahan hukum primer, sekunder dan tersier yang berkaitan dengan rumusan masalah penelitian ini akan diolah dan dianalisis berdasarkan analisis muatan untuk menghasilkan preskripsi dari rumusan masalah penelitian ini. Analisis bahan hukum dilakukan guna memperoleh jawaban atas isu hukum yang sedang dihadapi.

Sebagaimana dinyatakan oleh Peter Mahmud Marzuki,[24] analisis bahan hukum dapat dilakukan dengan langkah-langkah sebagai berikut:

1. Fakta-fakta hukum yang telah terkumpul, diidentifikasi dan hal-hal yang tidak relevan dihilangkan guna menetapkan isu hukum
2. Pengumpulan bahan-bahan hukum dan sekiranya dipandang mempunyai relevansi juga bahan-bahan non hukum
3. Melakukan telaah atas isu hukum yang diajukan berdasarkan bahan-bahan yang telah dikumpulkan;
4. Menarik kesimpulan dalam argumentasi yang menjawab isu hukum; dan
5. Memberikan preskripsi berdasarkan argumentasi yang telah dibangun didalam kesimpulan.

1.6 Sistematika Penelitian

Dalam rangka memperoleh gambaran yang jelas terhadap arah dan tujuan skripsi ini, maka secara garis besar dapat digambarkan melalui sistematika penulisan. Sistematika penulisan skripsi ini terdiri atas 4 (empat) bab, di mana masing-masing bab memiliki pokok-pokok bahasan penting.

Bab I Pendahuluan, di mana dalam bab tersebut memuat uraian mengenai latar belakang, rumusan masalah, tujuan penelitian, manfaat penelitian, metode penelitian dan sistematika penelitian. Latar belakang memuat uraian terhadap pertimbangan dan argumentasi penulis dalam mengkaji mengenai harmonisasi klausul fleksibilitas yang ada di dalam *TRIPs Agreement* dengan Pasal 20 Undang-Undang Nomor 13 Tahun 2016 tentang Paten yang berkaitan dengan importasi vaksin Covid-19. Rumusan masalah memuat 3 (tiga) persoalan di mana akan diuraikan dalam pemikiran teoritis yang kebenarannya perlu dianalisis. Ketiga rumusan masalah tersebut, diantaranya ada tidaknya fleksibilitas dalam Pasal 20 UU Paten, urgensi pengaturan klausul fleksibilitas *TRIPs Agreement* dan konsep ke depan mengenai harmonisasi fleksibilitas *TRIPs Agreement* dengan UU Paten. Adapun dalam bab ini terdapat tujuan penelitian, yang mana dibedakan

[24] *Ibid*, h. 213.

menjadi tujuan umum dan khusus. Demikian juga dengan manfaat penelitian yang mana meliputi manfaat teoretis dan manfaat praktis. Metode penelitian meliputi tipe penelitian, pendekatan penelitian, sumber bahan hukum, metode pengumpulan bahan hukum dan analisa bahan hukum. Sedangkan, sistematika penelitian menguraikan dari bagian awal sampai dengan bagian akhir skripsi.

Bab II Kajian Pustaka memuat penjelasan yang relevan dengan judul skripsi, di mana terdapat tinjauan pustaka dan landasan teori. Dalam tinjauan pustaka, penulis mengkaji penelitian-penelitian terdahulu yang relevan dengan topik yang sedang dibahas. Sedangkan, dalam landasan teori, penulis mengkaji teori-teori yang relevan dengan penelitian yang sedang dilakukan. Adapun dalam landasan teori ini, meliputi *TRIPs Agreement*, klausul fleksibilitas *TRIPs Agreement*, paten, importasi dan vaksin.

Bab III Hasil dan Pembahasan memuat analisis dan jawaban atas rumusan masalah tersebut, di mana dalam bab ini terdiri atas 3 (tiga) pokok bahasan. Pertama, analisis terkait *ratio legis* kewajiban pemegang paten membuat produk dan menggunakan proses di Indonesia. Kedua, akibat hukum atas penerapan klausul fleksibilitas *TRIPs Agreement* dalam Pasal 20 UU Paten. Ketiga, mekanisme pengadaan vaksin Covid-19 dengan menerapkan klausul fleksibilitas *TRIPs Agreement*.

Bab IV Penutup terdiri atas simpulan dan saran, di mana simpulan dimaksudkan sebagai pernyataan akhir dan jawaban atas rumusan masalah yang sedang diuraikan dalam bab pembahasan. Sedangkan, saran dimaksudkan sebagai bagian yang memuat masukan-masukan yang sifatnya konstruktif terhadap keberlanjutan penelitian yang telah dilakukan.

BAB 2
KAJIAN PUSTAKA

2.1 *Agreement on Trade-Related Aspects of Intellectual Property Rights* (*TRIPs Agreement*)

2.1.1 Tujuan Pembentukan *TRIPs Agreement*

Munculnya gagasan untuk melahirkan persetujuan *TRIPs Agreement* yang berlaku secara internasional didasarkan atas kondisi perdagangan dan ekonomi negara-negara di dunia yang semakin meluas serta tidak mengenal batas-batas negara. Oleh karena itu, negara-negara maju yang dalam hal ini diinisiasi oleh Amerika Serikat mengumumkan untuk melahirkan *TRIPs Agreement*. Tindakan tersebut dinilai sebagai langkah antisipasi di mana *World Intellectual Property Organization* (WIPO) tidak mampu melindungi HKI mereka di pasar global.[25] TRIPs mulai diberlakukan sejak tahun 1994, di mana hal tersebut dimaksudkan untuk meningkatkan perlindungan terhadap aspek-aspek HKI beserta inovasi-inovasinya, menjamin prosedur pelaksanaan HKI yang tidak menghambat kegiatan komersialisasi dan mengembangkan mekanisme kerjasama internasional dalam hal perdagangan.[26] Adapun lahirnya *TRIPs Agreement* ditujukan untuk melindungi dan menegakkan hukum HKI dalam rangka memacu inovasi-inovasi baru, membuka peluang atas pengalihan dan penyebaran teknologi dan memberikan manfaat kepada negara-negara anggota terhadap akses pengetahuan teknologi dalam rangka menciptakan kesejahteraan sosial dan ekonomi.[27]

2.1.2 Prinsip-Prinsip dalam *TRIPs Agreement*

Terdapat beberapa macam prinsip yang dimuat di dalam ketentuan *TRIPs Agreement*, diantaranya *Standard Minimal*, *National Treatment*, *Most-Favoured*

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[25] Siti Munawaroh, "Peranan TRIPs (*Trade Related-Aspect of Intellectual Property Rights*) Terhadap Hak Kekayaan Atas Intelektual di Bidang Teknologi Informasi di Indonesia", *Jurnal Teknologi Informasi DINAMIK*, Vol. XI, No. 1, Januari 2006, h. 24

[26] Maringan Lumbanradja, *Globalisasi HAKI Perdagangan dan Persaingan Pasar Bebas Potensi Intelektual, Industrial, Peradaban Implementasi TRIPs dan Internasional Treaties*, Program Magister Kenotariatan Ilmu Hukum Universitas Diponegoro, Semarang, 2010, h.14.

[27] Siti Munawaroh, op.cit, 25, h. 25.

National Treatment, Alih Teknologi dan Kesehatan Masyarakat serta Kepentingan Publik. Pertama, *Standard Minimum* sebagaimana tertuang di dalam *Article 1 Paragraph 1 TRIPs Agreement*[28] hanya memuat mengenai ketentuan-ketentuan minimum terhadap perlindungan dan penegakkan HKI yang wajib diterapkan oleh negara-negara anggota. Dengan demikian, adanya prinsip standar minimum, maka tidak ada larangan bagi negara-negara untuk menetapkan standar yang lebih tinggi. Namun, penetapan standar tersebut harus tetap memperhatikan ketentuan-ketentuan di dalam *TRIPs Agreement* dan prinsip-prinsip hukum internasional.[29]

Kedua, Prinsip *National Treatment* sebagaimana diatur di dalam *Article 3 TRIPs Agreement*[30] yang dimaksudkan untuk memberikan perlakuan yang sama terhadap warga negara baik dari negara sendiri maupun negara lain dalam kaitannya dengan perlindungan HKI. Senada dengan ketentuan tersebut, Michael Blakeney menyatakan bahwa prinsip National Treatment bertujuan untuk mengimpor prinsip-prinsip umum yang relevan dari Konvensi Paris, Konvensi Berne dan Konvensi Roma dan lebih menekankan perlindungan terhadap kekayaan intelektual warga negara.[31]

Ketiga, Prinsip *Most-Favoured National Treatment* sebagaimana dimuat dalam *Article 4 TRIPs Agreement*[32] berintikan bahwa pemberian suatu manfaat, keberpihakan, hak istimewa yang diberikan oleh suatu anggota negara kepada

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[28] *Article 1 Paragraph 1 state that member shall give effect to the provisions of this Agreement. Member may, but shall not be obliged to, implement in their law more extensive protection than this required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Member shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal systems and practice*.

[29] Achmad Zen Umar Purba, *Hak Kekayaan Intelektual Pasca TRIPs*, Edisi Pertama, Cet.1, Alumni, Bandung, 2005, h. 24.

[30] *Article 3 state that Each Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection3 of intellectual property, subject to the exceptions already provided in, respectively, the Paris Convention (1967), the Berne Convention (1971), the Rome Convention or the Treaty on Intellectual Property in Respect of Integrated Circuits. In respect of performers, producers of phonograms and broadcasting organizations, this obligation only applies in respect of the rights provided under this Agreement. Any Member availing itself of the possibilities provided in Article 6 of the Berne Convention (1971) or paragraph 1(b) of Article 16 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for TRIPS.*

[31] Achmad Zen Umar Purba, op.cit, h. 25.

[32] *Article 4 state that with regard to the protection of intellectual property, any advantage,favour,privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members.*

warga negara anggota lain harus diberikan dengan segera dan tanpa syarat. Berdasarkan ketentuan tersebut, maka garis besar prinsip ini dimaksudkan untuk memberikan perlakuan yang sama baik terhadap warga negara sendiri maupun warga negara lain.

Keempat, alih teknologi sebagaimana diatur dalam *Article 7 TRIPs Agreement*[33] menjadi dasar bagi negara-negara anggota khususnya negara berkembang untuk mendapatkan akses transfer teknologi dari negara maju. Dengan demikian, adanya prinsip tersebut diharapkan akan terjadi alih teknologi dengan tujuan pengembangan inovasi dan penyemaian teknologi untuk kepentingan bersama.

Kelima, prinsip kesehatan masyarakat dan kepentingan pubik sebagaimana diatur dalam *Article 8 TRIPs Agreement*[34] ditujukan kepada negara-negara anggota dalam rangka menyesuaikan undang-undang nasional mereka dengan ketentuan *TRIPs Agreement* diberikan kebebasan untuk mengadopsi berbagai langkah penting terhadap perlindungan kesehatan masyarakat.

2.1.3 Peranan *TRIPs Agreement* Terhadap HKI

Sebagaimana diketahui bahwa munculnya *TRIPs Agreement* telah mempengaruhi berbagai aspek baru terhadap perlindungan HKI dalam lingkup global. Beberapa aspek penting dari paten juga telah diperkenalkan dalam *TRIPs Agreement* khususnya di dalam bidang farmasi, diantaranya paten proses dan paten produk, jangka waktu perlindungan dan penggunaan lisensi wajib yang terbatas.[35] Akan tetapi, kemunculan *TRIPs Agreement* nyatanya tidak setujui oleh negara-negara berkembang dengan dengan alasan bahwa perjanjian tersebut

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[33] *Article 7 state that the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technologu, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.*

[34] *Article 8 state that member may, in formulating or amending their laws and regulations, adopts measures necessary to protect public health and nutritions, and to promote the public interest in sectors of vital importance to their socio-economic and technological development provided that such measures are consistent with the provision of this Agreement.*

[35] Nadia Natasha Seeratan, "The Negative Impact of Intellectual Property Patent Rights on Developing Countries: An Examination of the Indian Pharmaceutical Industries", *St. Mary's Law Review on Minority*, Issues 339, (2001), h. 13.

bertujuan untuk melestarikan monopoli negara-negara maju atas negara-negara berkembang di bidang ekonomi dan teknologi. Di samping itu, *TRIPs Agreement* juga diyakini oleh negara berkembang sebagai faktor yang akan memperbesar jurang pemisah antara kedua kelompok negara tersebut, terutama yang berkaitan dengan pembangunan ekonomi dan teknologi.[36]

Walaupun *TRIPs Agreement* dinilai sebagai perjanjian yang kontroversial oleh negara-negara berkembang, pada akhirnya mereka bersedia untuk menandatangani perjanjian tersebut dan tunduk pada standar internasional yang telah ditetapkannya.[37] Ketersediaan negara-negara berkembang untuk tunduk pada *TRIPs Agreement* didasarkan atas dua alasan. Pertama, negara-negara berkembang menggantungkan ekonominya pada dan penanaman modal asing dan pinjaman dari sponsor luar negeri. Di samping itu, negara-engara berkembang terpaksa memutuskan untuk tunduk pada *TRIPs Agreement* karena dengan keikutsertaan mereka dapat membantu perkembangan ekonomi negara mereka.[38] Alasan ini dinilai masuk akal, karena penundukan diri terhadap perjanjian tersebut akan menjadi salah satu syarat penting dalam menarik investor asing.[39] Kedua, *TRIPs Agreement* dijadikan salah satu persyaratan penting untuk menjadi anggota WTO.[40]

Dalam rangka meminimalisir kekhawatiran negara-negara berkembang tersebut, maka kebanyakan negara menyepakati untuk memasukkan beberapa fleksibilitas di dalam bidang kesehatan. *Article 8 TRIPs Agreement* sebagai salah satu pasal hasil kesepakatan antarnegara yang mana memberikan mandat kepada negara-negara anggota WTO untuk mengadopsi tindakan-tindakan yang perlu

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[36] Carlos Correa, *Integrating Public Health Concerns Into Patent Legislation in Developing Countries*, South Centre, Geneva, 2000, h. 3.

[37] H.S. Kartadjoemena, *GATT, WTO dan Hasil Uruguay Round*, UI Press, Jakarta, 1997, h. 253, dalam bukunya, Kartadjoemena menggunakan istilah "pil pahit" untuk menggambarkan adanya unsur keterpaksaan dari negara-negara berkembang.

[38] Myles S. Getlan, "TRIPs and Section 301: A Comparative Study in Trade Dispute Resolution", *34 Columbia Journal of Transnational Law 173*, 1995, h. 2-3.

[39] Cristoph Anton, "The Development of Intellectual Property Law in Indonesia: From Colonial to National Law", *International Review of Industrial Property and Copyright Law*, Vol. 3, 1991, h. 374.

[40] Marco CEJ Bronckers, "The Impact of TRIPs: Intellectual Property Protection in Developing Countries", *Common Market Law Review*, Vol. 31, 1994, h. 1248.

guna melindungi kesehatan masyarakat.[41] Sebagaimana diketahui bahwa *TRIPs Agreement* setidaknya berisikan 12 pasal yang memiliki kaitan erat dengan perlindungan paten obat-obatan[42] dan tiga pasal diantaranya mengenai kebijakan untuk menangani dampak paten obat, yang dikenal sebagai fleksibilitas *TRIPs Agreement* (*The TRIPs safeguards*).[43]

Dengan adanya fleksibilitas tersebut, maka setiap negara berpeluang untuk mengadakan perlindungan HKI yang sesuai dengan kebutuhan nasionalnya masing-masing dan tidak bertentangan dengan ketentuan *TRIPs Agreement*. Akan tetapi, dalam praktiknya timbul permasalahan yang berkaitan dengan sifat *TRIPs Agreement*, di mana ia tidak menyediakan standar hukum internasional atau persyaratan hukum yang seragam bagi negara-negara anggota WTO.[44] Akibatnya, pelaksanaan fleksibilitas tersebut, termasuk bagaimana menerjemahkan pasal-pasal tersebut, berbeda-beda di antara negara anggota WTO, khususnya antara negara berkembang dengan negara maju. Padahal kehadiran *TRIPs Agreement* memberikan peranan yang cukup besar terhadap aspek kekayaan intelektual, khususnya dalam kaitannya dengan penggunaan teknologi.

Sebagaimana diketahui bahwa negara-negara berkembang mempunyai kepentingan spesifik dalam bidang teknologi informasi. Sedangkan, teknologi informasi yang akan dilindungi di sini berkaitan dengan hak paten dan perlindungan terhadap informasi yang dirahasiakan.[45] Perlindungan terhadap teknologi tersebut dinilai penting sebab di tengah dampak dari pasar bebas saat ini, maka permintaan tergadap teknologi informasi semakin tinggi. Oleh karena

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41 Nabila Ansari, "International Patent Rights in a Post-Doha World", *International Trade Law Journal*, 57, 2002, h. 3.

42 *Article 8 Agreement on Trade-Related Aspects of Intellectual Property Rights.*

43 "Network for Monitoring The Impact of Globalization and TRIPs on Access to Medicines", (Report of a Meeting on Health Economics and Drugs, World Health Organization, Bangkok, Thailand, February 2001), hal. 17, di mana kedua belas pasal di dalam TRIPs tersebut terdiri dari Pasal 3 dan 4 (prinsip nondiskriminasi), Pasal 7 (tujuan TRIPs), Pasal 8 (perlindungan kesehatan masyarakat), Pasal 27 (paten produk dan proses serta pengecualian paten), Pasal 33 (perlindungan paten minimum selama 20 tahun), Pasal 34 (pembuktian terbalik untuk paten proses), Pasal 39 (perlindungan data), Pasal 65 dan 66 (pengaturan ketentuan transisi untuk negara-negara berkembang yang menjadi anggota WTO), Pasal 66 dan 67 (alih teknologi dan kerjasama teknis), Pasal 70 ayat (8) (mailbox filings), Pasal 71 ayat (1) (review).

44 Carlos Correa, op.cit, h. 3.

45 Siti Munawaroh, op.cit, h. 26.

itu, beberapa negara juga telah berlomba-lomba untuk menyediakan teknologi informasi yang banyak.[46] Tingginya permintaan terhadap teknologi informasi tersebut tidak menutup kemungkinan akan terjadi pelanggaran-pelanggaran terhadap bidang HKI.

2.2 Klausul Fleksibilitas

Salah satu perjanjian cakupan (*covered agreement*) dalam WTO yang harus dilaksanakan oleh Indonesia adalah *TRIPs Agreement*, yang mana mengatur mengenai perlindungan terhadap HKI.[47] Salah satu ketentuan HKI yang diatur dalam *TRIPs Agreement* berkaitan dengan perlindungan paten.[48] Dalam memberikan perlindungan paten, *TRPs Agreement* memberikan beberapa klausul fleksibilitas dalam penerapannya. Klausul diartikan sebegai suatu ketentuan yang terdapat di dalam suatu perjanjian, di mana salah satu pasalnya dapat diperluas atau dibatasi.[49] Dengan adanya fleksibilitas tersebut, maka setiap negara berpeluang untuk mengadakan perlindungan HKI yang sesuai dengan kebutuhan nasionalnya masing-masing dan tidak bertentangan dengan ketentuan *TRIPs Agreement*.[50] Adapun beberapa fleksibilitas yang diberikan oleh *TRIPs Agreement*, diantaranya berupa impor paralel (*parallel import*), lisensi wajib (*compulsory license*), pelaksanaan paten (*government use*) dan *bolar provision*.

Pertama, impor paralel (*parallel import*) sebagaimana diatur dalam *Article 6 TRIPs Agreement*[51] diartikan sebagai suatu tindakan importasi yang dilakukan tanpa adanya persetujuan dari pemegang paten.[52] WHO juga memberikan batasan

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[46] *Ibid*, h. 26-27.

[47] Iman Sunendar, Eka An Aqimuddin dan Andre Dzulman, "Pemanfaatan Model Fleksbilitisan Paten atas Obat dalam WTO-Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) oleh Indonesia Ditinjau dari UU No. 14 Tahun 2001 tentang Paten", Prosiding Seminar Nasional Penelitian dan PKM *Sosial, Ekonomi dan Humaniora*, 2014, h. 93.

[48] *Ibid.*

[49] KBBI Daring, "Klausul", Diakses dari https://kbbi.kemdikbud.go.id/entri/klausul, pada Rabu, 7 Oktober 2020.

[50] Carlos Correa, op.cit, h. 3.

[51] *Article 6 Agreement on Trade-Related Aspects of Intellectual Property Rights, state that "for the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."*

[52] Carlos Correa, op.cit, h. 4.

pengertian terhadap impor paralel bahwa *parallel importation is importation, without the consent of the patent holder, of a patented product marketed in another country either by the patent-holder or with the patent-holder's consent.*[53]

Kedua, lisensi wajib (*compulsory license*) yang diartikan sebagai kewenangan yang diberikan oleh suatu lembaga kehakiman kepada pihak ketiga untuk menggunakan suatu invensi yang telah dipatenkan tanpa meminta izin kepada pemegang paten karena alasan kepentingan umum.[54] Naomi A. Bass menyatakan bahwa lisensi wajib merupakan suatu langkah yang cukup efektif dalam rangka membantu negara-negara berkembang guna menyediakan akses yang lebih baik terhadap obat-obatan esensial.[55] Lisensi wajib ini tertuang di dalam *Article 31 TRIPs Agreement,* di mana penggunaan paten oleh pihak lain tanpa persetujuan tetap diperbolehkan apabila penggunaan paten tersebut memenuhi persyaratan.

Ketiga, pelaksanaan paten (*government use*), sama halnya dengan lisensi wajib, pelaksanaan paten oleh pemerintah juga diizinkan oleh *TRIPs Agreement* melalui ketentuan yang terdapat dalam Pasal 31. Semua persyaratan yang diperlukan untuk pemberlakuan pelaksanaan paten oleh pemerintah ini adalah sama dengan lisensi wajib, kecuali syarat perolehan izin awal dari pemegang paten tidaklah diperlukan dalam pelaksanaan paten oleh pemerintah.[56]

Keempat, *bolar provision* atau *Roche-Bolar Provision* diartikan sebagai suatu kebijakan yang mengizinkan pihak ketiga untuk melakukan pengujian, penggunaan dan pembuatan obat yang masih dilindungi paten untuk keperluan memperoleh izin edar dari otoritas pengawasan obat dan makanan sebelum obat tersebut habis masa perlindungan patennya. Dari perspektif hukum, dasar pembenar terhadap pemberlakuan *bolar provision* dapat ditemukan secara ekslisit di dalam *Article 30 TRIPs Agreement*, yang menyatakan bahwa *Members may*

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53 World Health Organization, *Network for Monitoring The Impact of Globalization and TRIPs on Access to Medicines*, WHO Essential Drugs and Medicines Policy, Geneva, 2002, h. 18.

54 James J. Wheaton, "Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984", *Catholic University Law Review*, 433, 1986, h. 12-13.

55 Carlos Correa, op.cit, h. xiii.

56 "Compulsory Licensing and Parallel Importing: What do They Mean? Will They Improve Access to Essential Drugs for People Living With HIV/AIDS?", loc. cit.

provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.[57]

2.3 Paten

2.3.1 Definisi Paten

Dalam hal menjelaskan paten dari sisi substansi tentunya akan begitu dipengaruhi oleh kajian-kajian yang bersifat normatif. Hal ini sejalan dengan konsep substansi hukum itu sendiri.[58] Sebagaimana dijelaskan dalam Pasal 1 angka 1 Undang-Undang Nomor 13 Tahun 2016 tentang Paten, paten diartikan sebagai suatu hak eksklusif yang diberikan oleh negara kepada inventor atas hasil invensinya di bidang teknologi untuk jangka waktu tertentu melaksanakan sendiri invensi tersebut atau memberikan persetujuan kepada pihak lain untuk melaksanakannya.[59] Selaras dengan pengertian sebagaimana ditegaskan dalam Undang-Undang Nomor 13 Tahun 2016 tentang Paten, *World Intellectual Property Organization* (WIPO)[60] juga memberikan batasan pengertian terhadap paten, yaitu hak yang memiliki kekuatan hukum yang diberikan berdasarkan undang-undang kepada seseorang untuk mengecualikan, untuk waktu yang terbatas, orang lain dari tindakan tertentu dalam kaitannya dengan mendeskripsikan penemuan baru; hak istimewa diberikan oleh otoritas pemerintah sebagai masalah hak kepada orang yang berhak untuk mengajukannya dan yang memenuhi persyaratan yang ditentukan.

Di sisi lain, dalam suatu literatur, Rachmadi Usman menyatakan bahwa paten diartikan sebagai hak istimewa yang diberikan oleh pemerintah kepada

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57 *Article 30 Agreement on Trade-Related Aspects of Intellectual Property Rights.*

58 Lawrence M. Friedman, *The Legal System: A Social Science Perspective*, Russel Sage Foundation, New York, 1975, h. 11-16. Dalam pandangan Lawrence M. Friedman, substansi hukum merupakan satu bagian dalam sistem hukum, di samping aspek struktur hukum dan budaya hukum.

59 Pasal 1 angka 1 Undang-Undang Nomor 13 Tahun 2016 tentang Paten.

60 WIPO (Organisasi HKI dunia) didirikan pada tahun 1970 dan merupakan badan khusus PBB sejak tahun 1974, berasal dari sekretariat Konvensi Paris dan Konvensi Bern yang dibuat pada tahun 1880-an. (Lindsey Tim, et al, *Hak Kekayaan Intelektual: Suatu Pengantar*, Alumni, Bandung, 2005, h. 28.)

penemu (inventor) atas penemuannya (invensinya) di bidang teknologi, baik dalam bentuk produk ataupun masih dalam proses.[61] Paten memiliki jagka waktu tertentu di mana orang lain dilarang menggunakan invensinya hingga jangak waktu tersebut berakhir, atau atas izin dari inventor yang bersangkutan.

2.3.2 Unsur-Unsur Paten

Berdasarkan batasan tersebut, maka jelas bahwa invensi yang telah dipatenkan menyebabkan timbulnya hak monopoli bagi inventornya. Di mana hak monopoli tersebut dinilai sebagai suatu penghargaan atas ide intelektualnya.[62] Dengan demikian, berangkat dari batasan pengertian tersebut, maka paten memiliki beberapa unsur.

Pertama, paten merupakan hak eksklusif, di mana paten diartikan sebagai suatu hak kebendaan yang sifatnya tidak berwujud (*intangible assets*) merupakan hak yang dimonopoli. Monopoli di sini berarti tidak semua orang dapat mempergunakan atau melaksanakan invensi tersebut tanpa adanya izin dari inventor. Adapun kegiatan-kegiatan yang tergolong sebagai hak monopoli inventor, diantaranya dalam hal produksi (*manufacturing*), penggunaan (*using*), penjualan (*selling*) dan perbuatan yang berkaitan dengan penjualan barang tersebut, seperti mengimpor dan menyimpan (*stocking*).[63]

Kedua, paten diberikan oleh negara kepada inventor, di mana hal ini berarti dalam rangka memperoleh hak paten, maka seorang inventor diharuskan mengajukan pendaftaran atas invensinya. Dalam hal pendaftaran ini, harus memperhatikan sisi substantif maupun administratif, maka setelah itu inventor akan diberikan hak eksklusif tersebut oleh negara. Pemberian paten hanya difokuskan terhadap invensi di bidang teknologi dan bukan untuk bidang di luar

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61 Rachmadi Usman, *Hukum Hak atas Kekayaan Intelektual: Perlindungan dan Dimensi Hukumnya di Indonesia*, Citra Aditya Bakti, Bandung, 2003, h. 205.
62 Ita Gambiro, *Hukum Paten*, Sebelas Printing, Jakarta, h. 1.
63 Muhammad Djumhana dan Djubaedillah, *Perkembangan Doktrin dan Teori Perlindungan Hak Kekayaan Intelektual*, Citra Aditya Bakti, Bandung, 2006, h. 116.

teknologi. Adapun teknologi yang dimaksud yaitu berupa ide (immateriil) yang diterapkan dalam proses industri.[64]

Ketiga, diberikannya jangka waktu tertentu dalam melaksanakan invensi. Artinya inventor yang memperoleh hak paten diberikan suatu kewajiban untuk melaksanakan invensinya atau dapat juga memberikan izin pada pihak lain yang ingin melaksanakan invensinya.[65]

2.3.3 Jenis-Jenis Paten

Mengenai jenis-jenis paten, Carl Roper[66] menyebutkan bahwa ada berbagai jenis paten yang dikelompokkan dalam bentuk suatu penggunaan, desain ataupun tanaman. Berkaitan dengan desain dan tanaman jenis baru juga dapat dikelompokkan sebagai suatu paten, akan tetapi dalam perkembangannya, keduanya telah mendapatkan perlindungan hukum sendiri dalam hukum desain industri dan perlindungan varietas tanaman.[67]

Adapun dalam konstruksi hukum Indonesia sebagaimana diatur di dalam Pasal 2 UU Paten, paten dikelompokkan menjadi paten biasa dan paten sederhana.[68] Paten biasa diartikan sebagai paten yang didapatkan melalui penelitian atau pengembangan mendalam lebih dari satu klaim. Sedangkan, paten sederhana diartikan sebagai paten yang tidak memerlukan penelitian atau pengembangan mendalam, melainkan hanya memuat satu klaim.[69]

Lebih lanjut, dalam Pasal 3 UU Paten menjelaskan bahwa perlindungan terhadap paten biasa diberikan kepada invensi baru, mengandung langkah inventif dan dapat diterapkan dalam industri.[70] Sedangkan, untuk perlindungan terhadap

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64 OK. Saidin, *Aspek Hukum Hak Kekayaan Intelektual*, RajaGrafindo Persada, Jakarta, 1995, h. 139-140.

65 Dea Melina Nugraheni, op.cit, h. 46.

66 Carl Roper, *Trade Secret Theft, Industrial Espionage and the China Threat*, Taylor & Francis Group, Boca Raton, 2014, h. 184, menyatakan bahwa "*There are three types of patents: utility, design and plant, with utility patents being the most common form. Utility patents are available for inventions that are novel, non-obvoius and useful*…".

67 Sujana Donandi, *Hukum Kekayaan Intelektual di Indonesia*, Deepublish, Sleman, 2019, h. 59.

68 Pasal 2 Undang-Undang Nomor 13 Tahun 2016 tentang Paten.

69 Dea Melina Nugraheni, op.cit, h. 47.

70 Pasal 3 ayat (1) Undang-Undang Nomor 13 Tahun 2016 tentang Paten.

paten sederhana diberikan kepada setiap invensi baru, pengembangan dari produk atau proses yang telah ada dan dapat diterapkan dalam industri.[71]

Di samping itu, masih ada beberapa jenis paten lain sebagaimana dikutip dari Muhammad Djumhana, diantaranya paten yang berdiri sendiri (*independent patent*), paten yang terkait dengan paten lainnya (*dependent patent*), paten tambahan (*patent of addition*) dan paten impor (*patent of importation*).[72] Paten yang berdiri sendiri (*independent patent*) diartikan sebagai paten yang tidak bergantung pada paten lainnya. Paten yang terkait dengan paten lainnya (*dependent patent*), diartikan sebagai paten yang memiliki keterkaitan antar paten yang lainnya dan kedua paten itu dalam bidang yang berkaitan. Paten tambahan (*patent of addition*) paten ini merupakan perbaikan, penambahan atau tambahan dari temuan yang asli. Sedangkan, paten impor (*patent of importation*) merupakan paten yang bersifat khusus karena telah dikenal di luar negeri dan negara yang memberikan paten lagi hanya memperkuat atau mengesahkannya lagi supaya berlaku di wilayah negara yang memberikan paten lagi.

2.3.4 Kewajiban Pemegang Paten

Untuk mendapatkan perlindungan paten, maka pemegang paten harus memperhatikan beberapa persyaratan sebagaimana diatur dalam Pasal 3 UU Paten, diantaranya adanya unsur kebaruan (*novelty*), mengandung langkah inventif dan dapat diterapkan dalam industri.

Pertama, adanya unsur kebaruan (*novelty*) sebagai persyaratan untuk suatu invensi dapat diberikan perlindungan paten (*patentability*)[73] sudah diatur dalam undang-undang sebelumnya. Unsur kebaruan ini merupakan salah satu syarat mutlak yang harus dipenuhi oleh pemegang paten. Bilamana ketika mendaftarkan patennya dan ternyata invensi tersebut telah ada sebelumnya, maka invensi tersebut tidak lagi mengandung unsur kebaruan. Sistem kebaruan sebagaimana dianut oleh Indonesia merupakan sistem kebaruan yang luas (*world wide*

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71 Pasal 3 ayat (2) Undang-Undang Nomor 13 Tahun 2016 tentang Paten.
72 Muhammad Djumhana dan Djubaedillah, op.cit, h. 121-122.
73 Rachmadi Usman, op.cit, h. 209.

novelty)[74] yang bersifat relatif. Di bidang farmasi, adanya unsur kebaruan biasanya meliputi tiga komponen, diantaranya a) Kombinasi dan persiapan dalam menyatukan dua atau lebih bahan atau senyawa aktif yang telah diketahui; b) Sistem baru dalam penggunaan obat; dan c) Komposisi dari bahan-bahan aktif yang disatukan untuk menciptakan suatu obat atau produk-produk farmasi lainnya.[75]

Kedua, dalam praktiknya, adanya invensi yang mengandung langkah inventif biasanya sulit dibuktikan. Hal tersebut dikarenakan pemeriksaan suatu invensi dibuat atas dasar apa yang dikenal umum dalam bidang kreasi tertentu, serta apakah menurut anggapan telah dikenal oleh para ahli di bidang invensi tersebut.[76] Sebagaimana ditemukan dalam berbagai undang-undang paten maupun perjanjian-perjanjian paten lainnya, istilah langkah inventif diartikan sebagai adanya perbedaan antara invensi yang diklaim dan yang telah ada sebelumnya yang tidak jelas/terduga (*nonobvious*).[77] Di bidang farmasi, adanya suatu invensi yang mengandung langkah inventif menjadi tantangan tersendiri bagi pemegang paten. Hal ini dikarenakan dalam formula bahan baku maupun senyawa aktif harus dibuktikan terlebih dahulu apakah mengandung langkah inventif didalamnya.

Ketiga, invensi harus dapat diterapkan dalam bidang industri. Invensi tersebut dapat diartikan sebagai produk, produk tersebut harus mampu dibuat secara berulang-ulang (secara massal) dengan kualitas yang sama. Sedangkan, jika invensi berupa proses, maka proses tersebut harus mampu dijalankan atau digunakan dalam praktik. Dengan demikian, suatu invensi yang dapat diberi perlindungan paten apabila invensi tersebut dapat diterapkan dalam praktik,

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[74] Endang Purwaningsih, *Perkembangan Hukum Intellectual Property Right: Kajian Hukum Terhadap Ha katas Kekayaan Intelektual Hukum Paten*, Ghalia Indonesia, Bogor, 2005, h. 222.

[75] P.W. Grubb, *Chemical Inventions in Patents for Chemicals, Pharmaceuticals and Biotechnology – Fundamentals of Global Law Practice and Strategy*, Press Oxford, 1999, h. 215.

[76] Marni Emma Mustafa, *Prinsip-Prinsip Beracara dalam Penegakan Hukum Paten di Indonesia Dikaitkan dengan TRIPs-WTO*, Alumni, Bandung, 2007, h. 75.

[77] Imam Sjahputra, *Hak atas Kekayaan Intelektual: Suatu Pengantar*, Harvarindo, Jakarta, 2007, h. 95-96.

didayagunakan secara berulang-ulang atau praktis dalam skala ekonomis bagi dunia industri.[78]

2.4 Importasi

Di tengah derasnya arus perdagangan internasional, importasi menjadi salah satu kegiatan penting dalam suatu negara guna mendapatkan produk yang sesuai dengan kebutuhan masyarakatnya. Pada dasarnya, istilah importasi berasal dari kata impor yang secara terminologi artinya sebagai suatu kegiatan memasukkan barang dan sebagainya yang berasal dari luar negeri.[79] Sedangkan, dalam *Black's Law Dictionary* menyebutkan bahwa impor yaitu di mana suatu produk yang dibawa ke suatu negara berasal dari negara asalnya.[80]

Di samping itu, secara etimologi, sebagaimana disebutkan oleh Djauhari Ahsjar bahwa impor yaitu memasukkan barang yang berasal dari luar negeri ke dalam wilayah pabean Indonesia dengan memenuhi ketentuan yang berlaku.[81] Selanjutnya, Hamdani menyatakan bahwa impor merupakan suatu bentuk pembelian barang dari luar negeri untuk dimasukkan ke dalam peredaran Republik Indonesia dan barang yang dibeli tersebut harus dilaporkan kepada Direktorat Jenderal Bea dan Cukai Departemen Keuangan.[82]

Di sisi lain, berdasarkan Pasal 1 angka 18 Undang-Undang Nomor 7 Tahun 2014 tentang Perdagangan, impor diartikan sebagai suatu kegiatan memasukkan barang kedalam wilayah pabean.[83] Sedangkan, istilah importasi menurut Kamus Besar Bahasa Indonesia yaitu pemasukan barang-barang dan sebagainya dari luar negeri.[84]

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78 Dea Melina Nugraheni, op.cit, h. 52.
79 Anton M. Moelyono, *Kamus Besar Bahasa Indonesia*, Balai Pustaka-Departemen Pendidikan dan Kebudayaan Republik Indonesia, Jakarta, 1988, h. 327.
80 Bryan A. Garner, *Black's Law Dictionary*, *Nith Edition*, Thompson Reuter, St. PaulMinnesota, 2009, h. 325.
81 Djauhari Ahsjar, *Pedoman Transaksi Ekspor & Impor*, Prestasi Pustaka, Jakarta, 2007, h. 153.
82 Hamdani, *Seluk Beluk Perdagangan Ekspor*, Yayasan Bina Usaha Niaga Indonesia, Jakarta, 2003, h. 2.
83 Pasal 1 angka 18 Undang-Undang Nomor 7 Tahun 2014 tentang Perdagangan.
84 KBBI Daring, "Importasi", Diakses dari https://kbbi.kemdikbud.go.id/entri/importasi, pada Rabu, 7 Oktober 2020.

Berdasarkan pengertian-pengertian yang diungkapkan baik oleh para sarjana maupun undang-undang, maka importasi dapat dimaknai sebagai suatu kegiatan memasukkan barang yang berasal dari luar negeri ke dalam wilayah Indonesia dengan memenuhi ketentuan-ketentuan yang berlaku.

2.5 Vaksin

Penemuan vaksin merupakan salah satu penemuan yang begitu penting dalam dunia kesehatan. Selama paruh terakhir abad ke-20, hamper semua penyakit yang dulunya umum dijumpai di dunia berubah menjadi langka sejak ditemukannya vaksin.[85] Pengembangan vaksin untuk pertama kalinya yaitu vaksin cacar yang dikembangkan oleh Edward Jenner, di mana ia menemukan bahwa orang yang minum susu dari sapi cacar, maka ia cenderung kebal terhadap penyakit cacar.[86]

Kemudian, Louis Pasteur mengembangkan penemuan vaksin Jenner dengan mengembangkan vaksin rabies (*antitoxin*). Hingga pada abad ke-19, undang-undang wajib vaksinasi disahkan.[87] Vaksin diartikan sebagai salah satu produk biologi yang rentan terhadap kerusakan dan kehilangan potensi jika tidak dikelola dengan baik. Apabila terjadi kerusakan terhadap vaksin dalam hal pengelolaannya, maka vaksin tidak dapat digunakan.[88]

Penggolongan vaksin dapat diketahui berdasarkan asal antigennya, yaitu kuman atau virus hidup yang dilemahkan (*live attenuated*) dan berisikan virus atau bakteri yang dibuat tidak aktif (*inactiavtid*).[89]

Pertama, vaksin *live attenuated* yang tersedia berasal dari dua mikroorganisme, diantaranya berasal dari virus (vaksin campak, polio, rubella, dan demam kuning) serta berasal dari bakteri, yaitu berupa vaksin *Bacillus Calmette Guerin* (BCG).

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85 Mandal, Wilkins, Dunbar M. *Penyakit Infeksi : Edisi Keenam*, Erlangga, Jakarta, 2012, h. 2.
86 *Ibid*, h. 4.
87 *Ibid*, h. 4-5.
88 Cahyono S., *Vaksinasi Cara Ampuh Cegah Penyakit Infeksi*, Penerbit Kanisius, Yogyakarta, 2010, h. 37.
89 Sunarti, *Pro Kontra Imunisasi*, Hanggar Kreator , Yogyakarta, 2012, h. 45.

Kedua, vaksin *iniactivated*, yang tersedia berasal seluruh sel virus yang inactivated, seperti influenza, polio, rabies dan hepatitis A. Sedangkan yang berasa dari seluruh bakteri yang inactivated, yaitu pertusis.[90]

Di samping itu, mengenai jenis vaksin yang beredar di Indonesia jenisnya cukup banyak baik yang digunakan oleh dokter ataupun bidan. Beberapa vaksin yang tersedia di Indonesia, diantaranya vaksin Bacillus Calmette Guerin (BCG), vaksin Tetanus dan Difteri (TD), vaksin jerap Tetanus Toxoid (TT), Vaksin Difteri Tetanus (DT), Vaksin Polio, Vaksin Campak, Vaksin Hepatitis B, Vaksin DTP-HB, Vaksin Meningokokus, Japanese Enchephalitis (JE), Haemofilus Influenza (Hib), Vaksin Anti Rabies (VAR)[91] dan Vaksin Covid-19 (yang sedang dalam pengembangan).

Perihal penciptaan dan pengembangan vaksin Covid-19 dilakukan oleh berbagai instansi dengan menggunakan berbagai platform teknologi, diantaranya penggunaan asam nukleat (DNA dan RNA), partikel yang menyerupai virus, peptide, vector virus (replikasi dan nonreplikasi), protein rekombinan dan virus yang tidak aktif.[92] Saat ini telah dikembangkan berbagai macam platform teknologi untuk mengembangkan virus, namun yang menjadi persoalan yaitu berkaitan dengan ketersediaan informasi mengenai antigen Covid-19 yang masih terbatas.

Sebagian besar, informasi yang telah tersedia digunakan untuk menginduksi antibodi agar dapat meredam *protein spike* pada virus. Namun, masih diteliti hubungan antar antibodi ini dengan reseptor manusia ACE2 (*Angiotensin-converting Enzyme*) pada penyakit ini. Pada kasus beberapa tahun belakangan dengan virus SARS menunjukkan potensi untuk dieksplor lebih dalam dan dikembangkan dalam pengujian *in-vivo* dikarenakan virus Covid-19 dapat dikatakan sebagai mutasi dari virus SARS yang sebelumnya telah ada.[93]

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90 *Ibid*, h. 47-48.

91 Kementerian Kesehatan RI, *Permenkes Nomor 42/2013 tentang Penyelenggaraan Imunisasi*, Kementerian Kesehatan RI, Jakarta, 2013, h. 3.

92 Thanh Le, T., Zacharias A., Arun K., Raul G. R., Stig T., Melanie S., dan Stephen M., *The COVID-19 Vaccine Development Landscape*, *Nature Reviews*, Drug Discovery, 10, 2020, h. 305-306.

93 *Ibid*, h. 6.

BAB 4
PENUTUP

4.1 Simpulan

Berdasarkan uraian pembahasan sebagaimana telah disampaikan di atas, maka dapat ditarik kesimpulan sebagai berikut:

1. *Ratio legis* terhadap kewajiban pemegang paten membuat produk dan menggunakan proses di Indonesia telah dimuat dalam undang-undang paten sebelum-sebelumnya. Oleh karena itu, mempertimbangkan uraian analisis sebelumnya, setidaknya terdapat 3 (tiga) rumusan yang penulis berikan:
   a. Dengan menambahkan norma ayat yang mengecualikan penerapan Pasal 20. Pengecualian yang dimaksud yaitu menyatakan bahwa importasi dianggap sebagai pelaksanaan paten oleh Pemegang Paten. Langkah importasi tersebut merupakan salah satu upaya untuk menguatkan hak eksklusifitas pemegang paten untuk melaksanakan sendiri haknya secara komersial.
   b. Dengan mengubah kata **wajib** menjadi **dapat** dalam ketentuan pemegang paten wajib membuat produk atau menggunakan proses di Indonesia dalam Pasal 20 UU Paten. Pembuatan produk atau penggunaan proses harus menunjang kepentingan kesehatan masyarakat, ekonomi nasional, metode bisnis nasional, percepatan alih teknologi, fasilitasi investasi, penyerapan tenaga kerja dalam negeri, penyerapan sumber daya kekayaan intelektual nasional, menguatkan lembaga riset nasional dan lembaga riset perguruan tinggi.
   c. Di samping itu, perlu ditambahkan norma baru dalam ayat (3) yang menegaskan bahwa dalam hal mewujudkan alih teknologi maka perlu adanya perjanjian kerjasama paten (PCT).

Sebagaimana diketahui bahwa ketentuan perjanjian tersebut tidak diatur secara tegas dalam Pasal 33 UU Paten.

2. Secara teori, fleksibilitas dalam *TRIPs Agreement* memberikan keuntungan bagi negara-negara yang tergabung dalam keanggotaan WTO. Beberapa sisi positifnya, diantaranya mampu meningkatkan posisi perdagangan dan investasi, mengembangkan inovasi, mendorong iklim persaingan secara kompetitif dalam lingkup global dan menunjang kepentingan ekspor. Selain itu, jika Indonesia secara proaktif menerapkan fleksibilitas tersebut, yaitu terjalinnya kerjasama dengan negara-negara lain, dapat melindungi kesejahteraan masyarakatnya, mengalihkan teknologi dan mengembangkan ekonominya sesuai dengan *TRIPs Agreement.*
3. Mekanisme pengadaan vaksin Covid-19 yang dapat diterapkan oleh Indonesia dengan mempertimbangkan fleksibilitas *TRIPs Agreement* terdapat 2 (dua) model, diantaranya:
   a. Pertama, dengan memberikan paten terhadap metode ataupun platform vaksin. Salah satu platform yang digunakan oleh Bio Pharma Indonesia yaitu melalui metode *inactivated virus* atau virus yang dimatikan dari Vaksin Sinovac. Sehingga metode tersebut dapat dipatenkan apabila memenuhi unsur *novelty and inventive step*. Dengan demikian, platform tersebut dapat dipatenkan apabila virus yang dimatikan tersebut telah dimodifikasi secara kimiawi.
   b. Kedua, model pemberian paten terhadap vaksin Covid-19 dapat dilakukan dengan melaksanakan Perjanjian Kerjasama Paten atau *The Patent Cooperation Treaty* (PCT). Kerjasama tersebut dimaksudkan untuk membantu pemohon dalam mencari perlindungan paten secara internasional untuk penemuan mereka dan memfasilitasi akses publik ke banyak informasi teknis yang berkaitan dengan penemuan tersebut.

4.2 Saran

Berdasarkan kesimpulan tersebut, maka terdapat beberapa hal yang menjadi perhatian dalam penangann paten ini, diantaranya:

1. Hendaknya pemerintah sebagai *stakeholder* dalam hal ini merevisi ketentuan-ketentuan yang terdapat dalam UU Paten khususnya Pasal 20 karena dinilai tidak sel s dengan perkembangan paten saat ini khususnya dalam bidang farmasi.
2. Hendaknya negara-negara berkembang yang tergabung dalam keanggotaan WTO –termasuk Indonesia– harus proaktif dalam menerapkan klausul-klausul fleksibilitas dalam *TRIPs Agreement.* Di mana dalam klausul-klausul tersebut terdapat berbagai sisi positif yang dapat diambil bersama pengalaman-pengalaman negara maju.
3. Hendaknya industri farmasi dalam negeri mengubah sikap yang awalnya menganggap bahwa investasi dalam bidang perdagangan jauh lebih menguntungkan daripada investasi dalam bidang produksi yang biasa melakukan riset dan pengembangan terhadap produk. Selain itu, industri farmasi dalam negeri juga diharapkan memiliki kemampuan untuk melakukan formulasi dan mengembangkan bahan baku obat, guna menunjang kemandirian produksi.

DAFTAR PUSTAKA

A. Buku

Abbott, Frederick, et. Al. 1999. *The International Intellectual Property System: Commentary and Materials*. The Hague: Kluwer Law International.

Ahsjar, Djauhari. 2007. *Pedoman Transaksi Ekspor & Impor*. Jakarta: Prestasi Pustaka.

Carl. 2014. *Trade Secret Theft, Industrial Espionage and the China Threat*. Boca Raton: Taylor & Francis Group.

Correa, Carlos. 2000. *Integrating Public Health Concerns Into Patent Legislation in Developing Countries*. Geneva: South Centre.

Garner, Bryan A. 2009. *Black's Law Dictionary, Nith Edition*. St. PaulMinnesota: Thompson Reuter.

Deere, Carolyn. 2009. *The Implementation Game: The TRIPs Agreement and the Global Politics of Intellectual Property Reform in Developing Countries*. New York: Oxford University Press.

Djumhana, Muhammad dan Djubaedillah. 2006. *Perkembangan Doktrin dan Teori Perlindungan Hak Kekayaan Intelektual*. Bandung: Citra Aditya Bakti.

Donandi, Sujana. 2019. *Hukum Kekayaan Intelektual di Indonesia*. Sleman: Deepublish.

Friedman, Lawrence M. 1975. *The Legal System: A Social Science Perspective*. New York: Russel Sage Foundation.

Gambiro, Ita. 1996. *Hukum Paten*. Jakarta: Sebelas Printing.

Grubb, P.W. 1999. *Chemical Inventions in Patents for Chemicals, Pharmaceuticals and Biotechnology – Fundamentals of Global Law Practice and Strategy*. Oxfordshire: Press Oxford.

Hamdani. 2003. *Seluk Beluk Perdagangan Ekspor*. Jakarta: Yayasan Bina Usaha Niaga Indonesia.

Hartono, C.F.G. Sunaryati. 1994. *Penelitian Hukum di Indonesia pada Akhir Abad ke-20*. Bandung: Penerbit Alumni.

Kartadjoemena, H.S. 1997. *GATT, WTO dan Hasil Uruguay Round*. Jakarta: UI Press.

Lumbanradja, Maringan. 2010. *Globalisasi HAKI Perdagangan dan Persaingan Pasar Bebas Potensi Intelektual, Industrial, Peradaban Implementasi TRIPs dan Internasional Treaties*. Semarang: Program Magister Kenotariatan Ilmu Hukum Universitas Diponegoro.

Maulana, Insan Budi. 1996. *Lisensi Paten.* Bandung: Citra Aditya Bakti.

----------. 1997. *Sukses Bisnis Melalui Merek, Paten dan Hak Cipta.* Bandung: Citra Aditya Bakti.

Mandal, Wilkins, Dunbar M. 2012. *Penyakit Infeksi : Edisi Keenam*. Jakarta: Erlangga.

Marzuki, Peter Mahmud. 2015. *Penelitian Hukum Edisi Revisi*. Jakarta: Kencana Prenada.

Maskus, K. 2000. *Intellectual Property Rights in the Global Economy*. Washington DC: Institute for International Economics (IIE).

Moelyono, Anton M. 1988. *Kamus Besar Bahasa Indonesia*. Jakarta: Balai Pustaka-Departemen Pendidikan dan Kebudayaan Republik Indonesia.

Mustafa, Marni Emma. 2007. *Prinsip-Prinsip Beracara dalam Penegakan Hukum Paten di Indonesia Dikaitkan dengan TRIPs-WTO*. Bandung: Alumni.

M. D, Moh. Mahfud. 2010. *Membangun Politik Hukum, Menegakkan Konstitusi*. Jakarta: Rajawali Pers.

Nasution, Johan. 2008. *Metode Penelitian Ilmu Hukum.* Bandung: Mandar Maju.

Notoatmodjo, Soekidjo. 1997. *Ilmu Kesehatan Masyarakat: Prinsip-Prinsip Dasar*. Jakarta: Rineka Cipta.

Nguyen, Tu Thanh. 2010. *Competition Law, Technology Transfer and the TRIPS Agreement: Implication for Developing Country.* Northampton-Massachusetss: Edward Elgar Publishing Limited.

Organization, World Health. 2002. *Network for Monitoring The Impact of Globalization and TRIPs on Access to Medicines*. Geneva: WHO Essential Drugs and Medicines Policy.

Priapantja, Cita Citrawinda 2003. *Hak Kekayaan Intelektual: Tantangan Masa Depan*. Jakarta: Badan Penerbit Fakultas Hukum Universitas Indonesia.

Purba, Achmad Zen Umar. 2005. *Hak Kekayaan Intelektual Pasca TRIPs*, Edisi Pertama, Cet.1. Bandung: Alumni.

Purwaningsih, Endang. 2005. *Perkembangan Hukum Intellectual Property Right: Kajian Hukum Terhadap Hak atas Kekayaan Intelektual Hukum Paten*. Bogor: Ghalia Indonesia.

----------. 2019. *Seri Hukum Hak Kekayaan Intelektual: Hukum Paten (Edisi Revisi).* Bandung: Mandar Maju.Roper,

RI, Kementerian Kesehatan. 2013. *Permenkes Nomor 42/2013 tentang Penyelenggaraan Imunisasi*. Jakarta: Kementerian Kesehatan RI.

Rooseno, Noorhadi dan Heraty. 1978. *Masalah Paten dalam Praktik.* Bandung: Bina Cipta.

Saidin, OK. 1995. *Aspek Hukum Hak Kekayaan Intelektual*. Jakarta: RajaGrafindo Persada.

Sardjono, Agus. 2009. *Membumikan HKI di Indonesia*. Bandung: Nuansa Aulia.

----------. 2010. *Hak Kekayaan Intelektual dan Pengetahuan Tradisional*. Bandung: Alumni.

Sjahputra, Imam. 2007. *Hak atas Kekayaan Intelektual: Suatu Pengantar*. Jakarta: Harvarindo.

S., Cahyono. 2010. *Vaksinasi Cara Ampuh Cegah Penyakit Infeksi*, Yogyakarta: Penerbit Kanisius.

Sumantoro. 1993. *Masalah Pengaturan Alih Teknologi*. Bandung: Alumni.

Sunarti. 2012. *Pro Kontra Imunisasi.* Yogyakarta: Hanggar Kreator.

Thanh Le, T., Zacharias A., Arun K., Raul G. R., Stig T., Melanie S., dan Stephen M., 2020, *The COVID-19 Vaccine Development Landscape*, *Nature Reviews*, Drug Discovery.

Tim, Lindsey, et al. 2005. *Hak Kekayaan Intelektual: Suatu Pengantar*. Bandung: Alumni.

----------. 2006. *Hak Kekayaan Intelektual Suatu Pengantar*. Bandung: Asian Law Group Pty & Alumni.

Treaty, Patent Cooperation. 1978. U.S.T., T.I.A.S. No. 8733, reprihted in 9 INT'L LEGAL MATERIALS 978 (1970).

Usman, Rachmadi. 2003. *Hukum Hak atas Kekayaan Intelektual: Perlindungan dan Dimensi Hukumnya di Indonesia*. Bandung: Citra Aditya Bakti.

Williams, Frederick & David V. Gibson. 1993. *Technology Transfer*. Newbury Park: Sage.

B. Peraturan Perundang-Undangan

Agreement on Trade-Related Aspects of Intellectual Property Rights.

Patent Cooperation Treaty.

Peraturan Menteri Hukum dan HAM Nomor 15 Tahun 2018 tentang Pelaksanaan Paten oleh Pemegang Paten.

Peraturan Presiden Nomor 99 Tahun 2020 tentang Pengadaan Vaksin dan Pelaksanaan Vaksinasi dalam Rangka Penanggulangan Pandemi *Corona Virus Disease 2019* (Covid-19).

Undang-Undang Nomor 7 Tahun 2014 tentang Perdagangan.

Undang-Undang Nomor 13 Tahun 2016 tentang Paten.

C. Makalah

AUSAID, IASTP, "Intellectual Property Rights" *Textbook*, Indonesia-Australia, 2002.

Ansari, Nabila, "International Patent Rights in a Post-Doha World", *International Trade Law Journal*, 57, 2002.

Anton, Cristoph. "The Development of Intellectual Property Law in Indonesia: From Colonial to National Law", *International Review of Industrial Property and Copyright Law*, Vol. 3, 1991.

BPHN, "Draft Naskah Akademik RUU Tentang Paten", Jakarta: Kementerian Hukum dan Hak Asasi Manusia Republik Indonesia, 2015.

--------, "Naskah Akademik Rancangan Undang-Undang Tentang Perubahan Atas Undang-Undang Republik Indonesia Nomor 13 Tahun 2016 Tentang

Paten", Kementerian Hukum dan Hak Asasi Manusia Republik Indonesia, Jakarta, 2019.

Bronckers, Marco CEJ, "The Impact of TRIPs: Intellectual Property Protection in Developing Countries", *Common Market Law Review*, Vol. 31, 1994.

Cardwell, Ryan dan Pascal L. Ghazalian, "The Effect of the TRIPs Agreement on International Protection of Intellectual Property Rights", *Department of Economics*, University of Lethbridge, Canada.

Commission, Australian Law Reform. "Genes and Ingenuity: Gene Patenting and Human Health*", Report No 99,* 2004.

Chadwick, Robin, Warren D. Woessner, Monique Perdok, and Janet Embretson, "Patenting Vaccines: A Look Back and the Road Ahead", *SLW INSTITUTE*, Building Extraordinary IP Assets, 2020.

Fox, Eleanor M., "Economic Development, Poverty and Antitrust: the Other Path", 2008, in Qaqaya Hassan and G. Lipimile (eds), *The Effects of Anti-competitive Business Practices on Developing Countries and Their Development Prospects*, UNCTAD, Geneva.

Getlan, Myles S., "TRIPs and Section 301: A Comparative Study in Trade Dispute Resolution", *34 Columbia Journal of Transnational Law 173*, 1995.

Ginarte, J.C. dan W.G. Park, "Determinants of Patent Rights: A Cross-national Study", *Research Policy 26*.

Gold, E Richard, "SARS Genome Patent: Symptom or Disease?", *The Lancet*, 2003 Edition.

Iida, Masato, "IP Trends on Covid-19 Vaccine Related Patents", *SHIGA*, International Patent Office, 2020.

Marzuki, Peter M., "Pengaturan Hukum terhadap Perusahaan-Perusahaan Transnasional di Indonesia", (Fungsi UUP dalam Pengalihan Teknologi Perusahaan-Perusahaan Transnasional di Indonesia), *Disertasi*, PPS UNAIR, Surabaya, 1993.

----------, "Luasnya Perlindungan Paten", *Jurnal Hukum UII*, No. 12, Vol. 6, 1999.

Masnun, Muh. Ali dan Dina Roszana, "Persoalan Pengaturan Kewajiban Pemegang Paten untuk Membuat Produk atau Meggunakan Proses di Indonesia", *Jurnal Hukum Ius Quia Iustum*, Vol. 26, No. 2, Mei 2019.

McKie, Edward F., "Patent Cooperation Treaty: A New Adventure in Internationality of Patents", *North Carolina Journal of International Law and Commercial Regulation*, Vol. 4, No. 3.

Munawaroh, Siti, "Peranan TRIPs (Trade Related-Aspect of Intellectual Property Rights) Terhadap Hak Kekayaan Atas Intelektual di Bidang Teknologi Informasi di Indonesia", *Jurnal Teknologi Informasi DINAMIK*, Vol. XI, No. 1, Januari 2006.

Nugraheni, Dea Melina, "Perlindungan Paten dan Fleksibilitas Persetujuan TRIPs di Bidang Farmasi di Indonesia", *Tesis*, Fakultas Hukum, Universitas Indonesia, Juli 2011.

N. Lurie, Melanie S., Richard H., dan Jane H., "Developing Covid-19 Vaccines at Pandemic Speed", *The New England Journal of Medicine, Perspective*, 2020.

Organization, World Health, "Network for Monitoring The Impact of Globalization and TRIPs on Access to Medicines", *Report of a Meeting on Health Economics and Drugs*, World Health Organization, Bangkok, Thailand, February 2001.

Organization, World Trade, "Report (2002) of the Working Group of the Interaction between Trade and Competition Policy to the General Council", WT/WGTCP/6.

Seeratan, Nadia Natasha, "The Negative Impact of Intellectual Property Patent Rights on Developing Countries: An Examination of the Indian Pharmaceutical Industries", *St. Mary's Law Review on Minority,* Issues 339, 2001.

Sitorus, Winner, "Kepentingan Umum dalam Perlindungan Paten", *Jurnal Yuridika*, Vol. 29 No. 1, 2014.

Sunendar, Iman Eka An Aqimuddin dan Andre Dzulman, "Pemanfaatan Model Fleksibilitas Paten atas Obat dalam WTO-Agreement on Trade Related

Aspects of Intellectual Property Rights (TRIPs) oleh Indonesia Ditinjau dari UU No. 14 Tahun 2001 tentang Paten", *Prosiding*, Sosial, Ekonomi dan Humaniora, h. 91.

Utomo, Tomi Suryo, Eksistensi "*The TRIPs Safeguards*" di dalam Perjanjian TRIPs: dalam Perspektif Kesehatan Masyarakat", *Mimbar Hukum*, Vol. 20, No. 2, Juni 2003.

Weick, Cynthia Wagner and Cynthia F. Eakin, "Independent Inventors and Innovation", *International Journal of Entrepreneurship and Innovation*, February 2005.

Wheaton, James J., "Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984", *Catholic University Law Review*, 433, 1986.

Yu, Peter, "SARS and the Patent Race: An Introduction to the "Patent Law, Social Policy, and Public Interest", *Symposium, Cardozo Arts and Entertainment Law Journal*, 2004.

Yuningsih, Rahmi, "Uji Klinik Coronavac dan Rencanan Vaksinasi Covid-19 Massal di Indonesia", Bidang Kesejahteraan Sosial, *INFO Singkat*, Kajian Singkat Terhadap Isu Aktual dan Strategis, Vol. XII, No. 16/II/Puslit/Agustus/2020.

D. Internet

DJKI, "Statistik Permohonan Paten Berdasarkan Negara Asal", Diakes dari https://statistik.dgip.go.id/statistik/production/paten_negara.php, pada Sabtu, 3 Oktober 2020.

Desfourina, Fransisca, "Dari Cut Nyak Dien Hingga Bung Karno, Ini 15 Quotes Heroik Pahlawan Nasional Melegenda", Diakses dari https://www.gramedia.com/blog/kumpulan-quotes-heroik-pahlawan-nasional-indonesia-melegenda/ pada 10 September 2020.

Ditjen Paten, Statistik Paten dalam http://www.dgip.go.id.

J. Corum, Denise G., dan Carl Z., "Corona Virus Tracker", The New York Times, Diakses dari https://www.nytimes.com/interactiv e/2020/science/coronaviru s-vaccine-tracker.html, pada 30 Desember 2020.

KBBI Daring, "Klausul", Diakses dari ps://kbbi.kemdikbud.go.id/entri/klausul, pada Rabu, 7 Oktober 2020.

----------, "Importasi", Diakses dari https://kbbi.kemdikbud.go.id/entri/importasi, pada Rabu, 7 Oktober 2020.

Kompas.com, "Daftar 5 Perusahaan Asing Pemasok Vaksin Corona di RI", Diakses dari https://money.kompas.com/read/2020/12/07/150600226/daftar-5-perusahaan-asing-pemasok-vaksin-corona-di-ri?page=all, pada Senin, 30 Desember 2020.

Kompas, Litbang, "Ketersediaan Produk Vaksin Covid-19 di Indonesia Bakal Semakin Beragam", Berdasarkan keterangan pers Menteri Kesehatan di Kantor Presiden, 29 Desember 2020, diakses dari https://bebas.kompas.id/baca/nusantara/2020/12/30/ketersediaan-produk-va ksin-covid-19-di-indonesia-bakal-semakin-beragam/, pada 31 Desember 2020.

Prasasti, Giovani Dio, "Disebut Tanpa Pengawet, Bio Farma Ungkap Kandungan Vaksin Covid-19 Sinovac", DIakses dari https://www.liputan6.com/health/read/4449135/disebut-tanpa-pengawet-bio-farma-ungkap-kandungan-vaksin-covid-19-sinovac, pada 5 Januari 2021.

Wang Xiaoyu dan Zhang Zhihao, "Experimental Covid Vaccine Gets Patent", Diakses dari https://www.chinadaily.com.cn /a/202008/18/WS5f3a88a2a31 0834817260d98.html, pada 2 Januari 2021.

E. Talkshow

Metro TV, 2020, *Wawancara dengan Menteri Badan Usaha Milik Negara (BUMN) dalam acara Indonesia Town Hall*, Metro TV, Jakarta, 20 November 2020.

LAMPIRAN

ANNEX 1C

AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS

AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS

Members,

Desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade;

Recognizing, to this end, the need for new rules and disciplines concerning:

(a) the applicability of the basic principles of GATT 1994 and of relevant international intellectual property agreements or conventions;

(b) the provision of adequate standards and principles concerning the availability, scope and use of trade-related intellectual property rights;

(c) the provision of effective and appropriate means for the enforcement of trade-related intellectual property rights, taking into account differences in national legal systems;

(d) the provision of effective and expeditious procedures for the multilateral prevention and settlement of disputes between governments; and

(e) transitional arrangements aiming at the fullest participation in the results of the negotiations;

Recognizing the need for a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods;

Recognizing that intellectual property rights are private rights;

Recognizing the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives;

Recognizing also the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base;

Emphasizing the importance of reducing tensions by reaching strengthened commitments to resolve disputes on trade-related intellectual property issues through multilateral procedures;

Desiring to establish a mutually supportive relationship between the WTO and the World Intellectual Property Organization (referred to in this Agreement as "WIPO") as well as other relevant international organizations;

Hereby agree as follows:

PART I

GENERAL PROVISIONS AND BASIC PRINCIPLES

Article 1

Nature and Scope of Obligations

1. Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

2. For the purposes of this Agreement, the term "intellectual property" refers to all categories of intellectual property that are the subject of Sections 1 through 7 of Part II.

3. Members shall accord the treatment provided for in this Agreement to the nationals of other Members.[1] In respect of the relevant intellectual property right, the nationals of other Members shall be understood as those natural or legal persons that would meet the criteria for eligibility for protection provided for in the Paris Convention (1967), the Berne Convention (1971), the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits, were all Members of the WTO members of those conventions.[2] Any Member availing itself of the possibilities provided in paragraph 3 of Article 5 or paragraph 2 of Article 6 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for Trade-Related Aspects of Intellectual Property Rights (the "Council for TRIPS").

Article 2

Intellectual Property Conventions

1. In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967).

2. Nothing in Parts I to IV of this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention, the Berne

[1] When "nationals" are referred to in this Agreement, they shall be deemed, in the case of a separate customs territory Member of the WTO, to mean persons, natural or legal, who are domiciled or who have a real and effective industrial or commercial establishment in that customs territory.

[2] In this Agreement, "Paris Convention" refers to the Paris Convention for the Protection of Industrial Property; "Paris Convention (1967)" refers to the Stockholm Act of this Convention of 14 July 1967. "Berne Convention" refers to the Berne Convention for the Protection of Literary and Artistic Works; "Berne Convention (1971)" refers to the Paris Act of this Convention of 24 July 1971. "Rome Convention" refers to the International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations, adopted at Rome on 26 October 1961. "Treaty on Intellectual Property in Respect of Integrated Circuits" (IPIC Treaty) refers to the Treaty on Intellectual Property in Respect of Integrated Circuits, adopted at Washington on 26 May 1989. "WTO Agreement" refers to the Agreement Establishing the WTO.

Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.

Article 3

National Treatment

1. Each Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection[3] of intellectual property, subject to the exceptions already provided in, respectively, the Paris Convention (1967), the Berne Convention (1971), the Rome Convention or the Treaty on Intellectual Property in Respect of Integrated Circuits. In respect of performers, producers of phonograms and broadcasting organizations, this obligation only applies in respect of the rights provided under this Agreement. Any Member availing itself of the possibilities provided in Article 6 of the Berne Convention (1971) or paragraph 1(b) of Article 16 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for TRIPS.

2. Members may avail themselves of the exceptions permitted under paragraph 1 in relation to judicial and administrative procedures, including the designation of an address for service or the appointment of an agent within the jurisdiction of a Member, only where such exceptions are necessary to secure compliance with laws and regulations which are not inconsistent with the provisions of this Agreement and where such practices are not applied in a manner which would constitute a disguised restriction on trade.

Article 4

Most-Favoured-Nation Treatment

With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members. Exempted from this obligation are any advantage, favour, privilege or immunity accorded by a Member:

(a) deriving from international agreements on judicial assistance or law enforcement of a general nature and not particularly confined to the protection of intellectual property;

(b) granted in accordance with the provisions of the Berne Convention (1971) or the Rome Convention authorizing that the treatment accorded be a function not of national treatment but of the treatment accorded in another country;

[3] For the purposes of Articles 3 and 4, "protection" shall include matters affecting the availability, acquisition, scope, maintenance and enforcement of intellectual property rights as well as those matters affecting the use of intellectual property rights specifically addressed in this Agreement.

(c) in respect of the rights of performers, producers of phonograms and broadcasting organizations not provided under this Agreement;

(d) deriving from international agreements related to the protection of intellectual property which entered into force prior to the entry into force of the WTO Agreement, provided that such agreements are notified to the Council for TRIPS and do not constitute an arbitrary or unjustifiable discrimination against nationals of other Members.

Article 5

Multilateral Agreements on Acquisition or Maintenance of Protection

The obligations under Articles 3 and 4 do not apply to procedures provided in multilateral agreements concluded under the auspices of WIPO relating to the acquisition or maintenance of intellectual property rights.

Article 6

Exhaustion

For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

Article 7

Objectives

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 8

Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

PART II

STANDARDS CONCERNING THE AVAILABILITY, SCOPE AND USE OF INTELLECTUAL PROPERTY RIGHTS

SECTION 1: COPYRIGHT AND RELATED RIGHTS

Article 9

Relation to the Berne Convention

1. Members shall comply with Articles 1 through 21 of the Berne Convention (1971) and the Appendix thereto. However, Members shall not have rights or obligations under this Agreement in respect of the rights conferred under Article 6*bis* of that Convention or of the rights derived therefrom.

2. Copyright protection shall extend to expressions and not to ideas, procedures, methods of operation or mathematical concepts as such.

Article 10

Computer Programs and Compilations of Data

1. Computer programs, whether in source or object code, shall be protected as literary works under the Berne Convention (1971).

2. Compilations of data or other material, whether in machine readable or other form, which by reason of the selection or arrangement of their contents constitute intellectual creations shall be protected as such. Such protection, which shall not extend to the data or material itself, shall be without prejudice to any copyright subsisting in the data or material itself.

Article 11

Rental Rights

In respect of at least computer programs and cinematographic works, a Member shall provide authors and their successors in title the right to authorize or to prohibit the commercial rental to the public of originals or copies of their copyright works. A

Member shall be excepted from this obligation in respect of cinematographic works unless such rental has led to widespread copying of such works which is materially impairing the exclusive right of reproduction conferred in that Member on authors and their successors in title. In respect of computer programs, this obligation does not apply to rentals where the program itself is not the essential object of the rental.

Article 12

Term of Protection

Whenever the term of protection of a work, other than a photographic work or a work of applied art, is calculated on a basis other than the life of a natural person, such term shall be no less than 50 years from the end of the calendar year of authorized publication, or, failing such authorized publication within 50 years from the making of the work, 50 years from the end of the calendar year of making.

Article 13

Limitations and Exceptions

Members shall confine limitations or exceptions to exclusive rights to certain special cases which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right holder.

Article 14

Protection of Performers, Producers of Phonograms (Sound Recordings) and Broadcasting Organizations

1. In respect of a fixation of their performance on a phonogram, performers shall have the possibility of preventing the following acts when undertaken without their authorization: the fixation of their unfixed performance and the reproduction of such fixation. Performers shall also have the possibility of preventing the following acts when undertaken without their authorization: the broadcasting by wireless means and the communication to the public of their live performance.

2. Producers of phonograms shall enjoy the right to authorize or prohibit the direct or indirect reproduction of their phonograms.

3. Broadcasting organizations shall have the right to prohibit the following acts when undertaken without their authorization: the fixation, the reproduction of fixations, and the rebroadcasting by wireless means of broadcasts, as well as the communication to the public of television broadcasts of the same. Where Members do not grant such rights to broadcasting organizations, they shall provide owners of copyright in the subject matter of broadcasts with the possibility of preventing the above acts, subject to the provisions of the Berne Convention (1971).

4. The provisions of Article 11 in respect of computer programs shall apply *mutatis mutandis* to producers of phonograms and any other right holders in phonograms as determined in a Member's law. If on 15 April 1994 a Member has in force a system of equitable remuneration of right holders in respect of the rental of phonograms, it may maintain such system provided that the commercial rental of phonograms is not giving rise to the material impairment of the exclusive rights of reproduction of right holders.

5. The term of the protection available under this Agreement to performers and producers of phonograms shall last at least until the end of a period of 50 years computed from the end of the calendar year in which the fixation was made or the performance took place. The term of protection granted pursuant to paragraph 3 shall last for at least 20 years from the end of the calendar year in which the broadcast took place.

6. Any Member may, in relation to the rights conferred under paragraphs 1, 2 and 3, provide for conditions, limitations, exceptions and reservations to the extent permitted by the Rome Convention. However, the provisions of Article 18 of the Berne Convention (1971) shall also apply, *mutatis mutandis*, to the rights of performers and producers of phonograms in phonograms.

SECTION 2: TRADEMARKS

Article 15

Protectable Subject Matter

1. Any sign, or any combination of signs, capable of distinguishing the goods or services of one undertaking from those of other undertakings, shall be capable of constituting a trademark. Such signs, in particular words including personal names, letters, numerals, figurative elements and combinations of colours as well as any combination of such signs, shall be eligible for registration as trademarks. Where signs are not inherently capable of distinguishing the relevant goods or services, Members may make registrability depend on distinctiveness acquired through use. Members may require, as a condition of registration, that signs be visually perceptible.

2. Paragraph 1 shall not be understood to prevent a Member from denying registration of a trademark on other grounds, provided that they do not derogate from the provisions of the Paris Convention (1967).

3. Members may make registrability depend on use. However, actual use of a trademark shall not be a condition for filing an application for registration. An application shall not be refused solely on the ground that intended use has not taken place before the expiry of a period of three years from the date of application.

4. The nature of the goods or services to which a trademark is to be applied shall in no case form an obstacle to registration of the trademark.

5. Members shall publish each trademark either before it is registered or promptly after it is registered and shall afford a reasonable opportunity for petitions to cancel the

registration. In addition, Members may afford an opportunity for the registration of a trademark to be opposed.

Article 16

Rights Conferred

1. The owner of a registered trademark shall have the exclusive right to prevent all third parties not having the owner's consent from using in the course of trade identical or similar signs for goods or services which are identical or similar to those in respect of which the trademark is registered where such use would result in a likelihood of confusion. In case of the use of an identical sign for identical goods or services, a likelihood of confusion shall be presumed. The rights described above shall not prejudice any existing prior rights, nor shall they affect the possibility of Members making rights available on the basis of use.

2. Article 6*bis* of the Paris Convention (1967) shall apply, *mutatis mutandis*, to services. In determining whether a trademark is well-known, Members shall take account of the knowledge of the trademark in the relevant sector of the public, including knowledge in the Member concerned which has been obtained as a result of the promotion of the trademark.

3. Article 6*bis* of the Paris Convention (1967) shall apply, *mutatis mutandis*, to goods or services which are not similar to those in respect of which a trademark is registered, provided that use of that trademark in relation to those goods or services would indicate a connection between those goods or services and the owner of the registered trademark and provided that the interests of the owner of the registered trademark are likely to be damaged by such use.

Article 17

Exceptions

Members may provide limited exceptions to the rights conferred by a trademark, such as fair use of descriptive terms, provided that such exceptions take account of the legitimate interests of the owner of the trademark and of third parties.

Article 18

Term of Protection

Initial registration, and each renewal of registration, of a trademark shall be for a term of no less than seven years. The registration of a trademark shall be renewable indefinitely.

Article 19

Requirement of Use

1. If use is required to maintain a registration, the registration may be cancelled only after an uninterrupted period of at least three years of non-use, unless valid reasons based on the existence of obstacles to such use are shown by the trademark owner. Circumstances arising independently of the will of the owner of the trademark which constitute an obstacle to the use of the trademark, such as import restrictions on or other government requirements for goods or services protected by the trademark, shall be recognized as valid reasons for non-use.

2. When subject to the control of its owner, use of a trademark by another person shall be recognized as use of the trademark for the purpose of maintaining the registration.

Article 20

Other Requirements

The use of a trademark in the course of trade shall not be unjustifiably encumbered by special requirements, such as use with another trademark, use in a special form or use in a manner detrimental to its capability to distinguish the goods or services of one undertaking from those of other undertakings. This will not preclude a requirement prescribing the use of the trademark identifying the undertaking producing the goods or services along with, but without linking it to, the trademark distinguishing the specific goods or services in question of that undertaking.

Article 21

Licensing and Assignment

Members may determine conditions on the licensing and assignment of trademarks, it being understood that the compulsory licensing of trademarks shall not be permitted and that the owner of a registered trademark shall have the right to assign the trademark with or without the transfer of the business to which the trademark belongs.

SECTION 3: GEOGRAPHICAL INDICATIONS

Article 22

Protection of Geographical Indications

1. Geographical indications are, for the purposes of this Agreement, indications which identify a good as originating in the territory of a Member, or a region or locality

in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin.

2. In respect of geographical indications, Members shall provide the legal means for interested parties to prevent:

(a) the use of any means in the designation or presentation of a good that indicates or suggests that the good in question originates in a geographical area other than the true place of origin in a manner which misleads the public as to the geographical origin of the good;

(b) any use which constitutes an act of unfair competition within the meaning of Article 10*bis* of the Paris Convention (1967).

3. A Member shall, *ex officio* if its legislation so permits or at the request of an interested party, refuse or invalidate the registration of a trademark which contains or consists of a geographical indication with respect to goods not originating in the territory indicated, if use of the indication in the trademark for such goods in that Member is of such a nature as to mislead the public as to the true place of origin.

4. The protection under paragraphs 1, 2 and 3 shall be applicable against a geographical indication which, although literally true as to the territory, region or locality in which the goods originate, falsely represents to the public that the goods originate in another territory.

Article 23

Additional Protection for Geographical Indications for Wines and Spirits

1. Each Member shall provide the legal means for interested parties to prevent use of a geographical indication identifying wines for wines not originating in the place indicated by the geographical indication in question or identifying spirits for spirits not originating in the place indicated by the geographical indication in question, even where the true origin of the goods is indicated or the geographical indication is used in translation or accompanied by expressions such as "kind", "type", "style", "imitation" or the like.[4]

2. The registration of a trademark for wines which contains or consists of a geographical indication identifying wines or for spirits which contains or consists of a geographical indication identifying spirits shall be refused or invalidated, *ex officio* if a Member's legislation so permits or at the request of an interested party, with respect to such wines or spirits not having this origin.

3. In the case of homonymous geographical indications for wines, protection shall be accorded to each indication, subject to the provisions of paragraph 4 of Article 22.

[4] Notwithstanding the first sentence of Article 42, Members may, with respect to these obligations, instead provide for enforcement by administrative action.

Each Member shall determine the practical conditions under which the homonymous indications in question will be differentiated from each other, taking into account the need to ensure equitable treatment of the producers concerned and that consumers are not misled.

4. In order to facilitate the protection of geographical indications for wines, negotiations shall be undertaken in the Council for TRIPS concerning the establishment of a multilateral system of notification and registration of geographical indications for wines eligible for protection in those Members participating in the system.

Article 24

International Negotiations; Exceptions

1. Members agree to enter into negotiations aimed at increasing the protection of individual geographical indications under Article 23. The provisions of paragraphs 4 through 8 below shall not be used by a Member to refuse to conduct negotiations or to conclude bilateral or multilateral agreements. In the context of such negotiations, Members shall be willing to consider the continued applicability of these provisions to individual geographical indications whose use was the subject of such negotiations.

2. The Council for TRIPS shall keep under review the application of the provisions of this Section; the first such review shall take place within two years of the entry into force of the WTO Agreement. Any matter affecting the compliance with the obligations under these provisions may be drawn to the attention of the Council, which, at the request of a Member, shall consult with any Member or Members in respect of such matter in respect of which it has not been possible to find a satisfactory solution through bilateral or plurilateral consultations between the Members concerned. The Council shall take such action as may be agreed to facilitate the operation and further the objectives of this Section.

3. In implementing this Section, a Member shall not diminish the protection of geographical indications that existed in that Member immediately prior to the date of entry into force of the WTO Agreement.

4. Nothing in this Section shall require a Member to prevent continued and similar use of a particular geographical indication of another Member identifying wines or spirits in connection with goods or services by any of its nationals or domiciliaries who have used that geographical indication in a continuous manner with regard to the same or related goods or services in the territory of that Member either (*a*) for at least 10 years preceding 15 April 1994 or (*b*) in good faith preceding that date.

5. Where a trademark has been applied for or registered in good faith, or where rights to a trademark have been acquired through use in good faith either:

(a) before the date of application of these provisions in that Member as defined in Part VI; or

(b) before the geographical indication is protected in its country of origin;

measures adopted to implement this Section shall not prejudice eligibility for or the validity of the registration of a trademark, or the right to use a trademark, on the basis that such a trademark is identical with, or similar to, a geographical indication.

6. Nothing in this Section shall require a Member to apply its provisions in respect of a geographical indication of any other Member with respect to goods or services for which the relevant indication is identical with the term customary in common language as the common name for such goods or services in the territory of that Member. Nothing in this Section shall require a Member to apply its provisions in respect of a geographical indication of any other Member with respect to products of the vine for which the relevant indication is identical with the customary name of a grape variety existing in the territory of that Member as of the date of entry into force of the WTO Agreement.

7. A Member may provide that any request made under this Section in connection with the use or registration of a trademark must be presented within five years after the adverse use of the protected indication has become generally known in that Member or after the date of registration of the trademark in that Member provided that the trademark has been published by that date, if such date is earlier than the date on which the adverse use became generally known in that Member, provided that the geographical indication is not used or registered in bad faith.

8. The provisions of this Section shall in no way prejudice the right of any person to use, in the course of trade, that person's name or the name of that person's predecessor in business, except where such name is used in such a manner as to mislead the public.

9. There shall be no obligation under this Agreement to protect geographical indications which are not or cease to be protected in their country of origin, or which have fallen into disuse in that country.

SECTION 4: INDUSTRIAL DESIGNS

Article 25

Requirements for Protection

1. Members shall provide for the protection of independently created industrial designs that are new or original. Members may provide that designs are not new or original if they do not significantly differ from known designs or combinations of known design features. Members may provide that such protection shall not extend to designs dictated essentially by technical or functional considerations.

2. Each Member shall ensure that requirements for securing protection for textile designs, in particular in regard to any cost, examination or publication, do not unreasonably impair the opportunity to seek and obtain such protection. Members shall be free to meet this obligation through industrial design law or through copyright law.

Article 26

Protection

1. The owner of a protected industrial design shall have the right to prevent third parties not having the owner's consent from making, selling or importing articles bearing or embodying a design which is a copy, or substantially a copy, of the protected design, when such acts are undertaken for commercial purposes.

2. Members may provide limited exceptions to the protection of industrial designs, provided that such exceptions do not unreasonably conflict with the normal exploitation of protected industrial designs and do not unreasonably prejudice the legitimate interests of the owner of the protected design, taking account of the legitimate interests of third parties.

3. The duration of protection available shall amount to at least 10 years.

SECTION 5: PATENTS

Article 27

Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents 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.[5] Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall

[5] For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.

provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Article 28

Rights Conferred

1. A patent shall confer on its owner the following exclusive rights:

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing[6] for these purposes that product;

(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

Article 29

Conditions on Patent Applicants

1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.

2. Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants.

Article 30

Exceptions to Rights Conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

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[6] This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6.

Article 31

Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use[7] of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

[7] "Other use" refers to use other than that allowed under Article 30.

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

Article 32

Revocation/Forfeiture

An opportunity for judicial review of any decision to revoke or forfeit a patent shall be available.

Article 33

Term of Protection

The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.[8]

Article 34

Process Patents: Burden of Proof

1. For the purposes of civil proceedings in respect of the infringement of the rights of the owner referred to in paragraph 1(b) of Article 28, if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process. Therefore, Members shall provide, in at least one of the following circumstances, that any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process:

(a) if the product obtained by the patented process is new;

(b) if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used.

2. Any Member shall be free to provide that the burden of proof indicated in paragraph 1 shall be on the alleged infringer only if the condition referred to in subparagraph (a) is fulfilled or only if the condition referred to in subparagraph (b) is fulfilled.

3. In the adduction of proof to the contrary, the legitimate interests of defendants in protecting their manufacturing and business secrets shall be taken into account.

SECTION 6: LAYOUT-DESIGNS (TOPOGRAPHIES) OF INTEGRATED CIRCUITS

Article 35

Relation to the IPIC Treaty

Members agree to provide protection to the layout-designs (topographies) of integrated circuits (referred to in this Agreement as "layout-designs") in accordance with Articles 2 through 7 (other than paragraph 3 of Article 6), Article 12 and paragraph 3 of Article 16 of the Treaty on Intellectual Property in Respect of Integrated Circuits and, in addition, to comply with the following provisions.

Article 36

[8] It is understood that those Members which do not have a system of original grant may provide that the term of protection shall be computed from the filing date in the system of original grant.

Scope of the Protection

Subject to the provisions of paragraph 1 of Article 37, Members shall consider unlawful the following acts if performed without the authorization of the right holder:[9] importing, selling, or otherwise distributing for commercial purposes a protected layout-design, an integrated circuit in which a protected layout-design is incorporated, or an article incorporating such an integrated circuit only in so far as it continues to contain an unlawfully reproduced layout-design.

Article 37

Acts Not Requiring the Authorization of the Right Holder

1. Notwithstanding Article 36, no Member shall consider unlawful the performance of any of the acts referred to in that Article in respect of an integrated circuit incorporating an unlawfully reproduced layout-design or any article incorporating such an integrated circuit where the person performing or ordering such acts did not know and had no reasonable ground to know, when acquiring the integrated circuit or article incorporating such an integrated circuit, that it incorporated an unlawfully reproduced layout-design. Members shall provide that, after the time that such person has received sufficient notice that the layout-design was unlawfully reproduced, that person may perform any of the acts with respect to the stock on hand or ordered before such time, but shall be liable to pay to the right holder a sum equivalent to a reasonable royalty such as would be payable under a freely negotiated licence in respect of such a layout-design.

2. The conditions set out in subparagraphs (a) through (k) of Article 31 shall apply *mutatis mutandis* in the event of any non-voluntary licensing of a layout-design or of its use by or for the government without the authorization of the right holder.

Article 38

Term of Protection

1. In Members requiring registration as a condition of protection, the term of protection of layout-designs shall not end before the expiration of a period of 10 years counted from the date of filing an application for registration or from the first commercial exploitation wherever in the world it occurs.

2. In Members not requiring registration as a condition for protection, layout-designs shall be protected for a term of no less than 10 years from the date of the first commercial exploitation wherever in the world it occurs.

3. Notwithstanding paragraphs 1 and 2, a Member may provide that protection shall lapse 15 years after the creation of the layout-design.

[9] The term "right holder" in this Section shall be understood as having the same meaning as the term "holder of the right" in the IPIC Treaty.

SECTION 7: PROTECTION OF UNDISCLOSED INFORMATION

Article 39

1. In the course of ensuring effective protection against unfair competition as provided in Article 10*bis* of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.

2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices[10] so long as such information:

(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

(b) has commercial value because it is secret; and

(c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

SECTION 8: CONTROL OF ANTI-COMPETITIVE PRACTICES IN CONTRACTUAL LICENCES

Article 40

1. Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology.

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[10] For the purpose of this provision, "a manner contrary to honest commercial practices" shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.

2. Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member.

3. Each Member shall enter, upon request, into consultations with any other Member which has cause to believe that an intellectual property right owner that is a national or domiciliary of the Member to which the request for consultations has been addressed is undertaking practices in violation of the requesting Member's laws and regulations on the subject matter of this Section, and which wishes to secure compliance with such legislation, without prejudice to any action under the law and to the full freedom of an ultimate decision of either Member. The Member addressed shall accord full and sympathetic consideration to, and shall afford adequate opportunity for, consultations with the requesting Member, and shall cooperate through supply of publicly available non-confidential information of relevance to the matter in question and of other information available to the Member, subject to domestic law and to the conclusion of mutually satisfactory agreements concerning the safeguarding of its confidentiality by the requesting Member.

4. A Member whose nationals or domiciliaries are subject to proceedings in another Member concerning alleged violation of that other Member's laws and regulations on the subject matter of this Section shall, upon request, be granted an opportunity for consultations by the other Member under the same conditions as those foreseen in paragraph 3.

PART III

ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS

SECTION 1: GENERAL OBLIGATIONS

Article 41

1. Members shall ensure that enforcement procedures as specified in this Part are available under their law so as to permit effective action against any act of infringement of intellectual property rights covered by this Agreement, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements. These procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.

2. Procedures concerning the enforcement of intellectual property rights shall be fair and equitable. They shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays.

3. Decisions on the merits of a case shall preferably be in writing and reasoned. They shall be made available at least to the parties to the proceeding without undue delay. Decisions on the merits of a case shall be based only on evidence in respect of which parties were offered the opportunity to be heard.

4. Parties to a proceeding shall have an opportunity for review by a judicial authority of final administrative decisions and, subject to jurisdictional provisions in a Member's law concerning the importance of a case, of at least the legal aspects of initial judicial decisions on the merits of a case. However, there shall be no obligation to provide an opportunity for review of acquittals in criminal cases.

5. It is understood that this Part does not create any obligation to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of Members to enforce their law in general. Nothing in this Part creates any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general.

SECTION 2: CIVIL AND ADMINISTRATIVE PROCEDURES AND REMEDIES

Article 42

Fair and Equitable Procedures

Members shall make available to right holders[11] civil judicial procedures concerning the enforcement of any intellectual property right covered by this Agreement. Defendants shall have the right to written notice which is timely and contains sufficient detail, including the basis of the claims. Parties shall be allowed to be represented by independent legal counsel, and procedures shall not impose overly burdensome requirements concerning mandatory personal appearances. All parties to such procedures shall be duly entitled to substantiate their claims and to present all relevant evidence. The procedure shall provide a means to identify and protect confidential information, unless this would be contrary to existing constitutional requirements.

Article 43

Evidence

1. The judicial authorities shall have the authority, where a party has presented reasonably available evidence sufficient to support its claims and has specified evidence relevant to substantiation of its claims which lies in the control of the opposing party, to order that this evidence be produced by the opposing party, subject in appropriate cases to conditions which ensure the protection of confidential information.

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[11] For the purpose of this Part, the term "right holder" includes federations and associations having legal standing to assert such rights.

2. In cases in which a party to a proceeding voluntarily and without good reason refuses access to, or otherwise does not provide necessary information within a reasonable period, or significantly impedes a procedure relating to an enforcement action, a Member may accord judicial authorities the authority to make preliminary and final determinations, affirmative or negative, on the basis of the information presented to them, including the complaint or the allegation presented by the party adversely affected by the denial of access to information, subject to providing the parties an opportunity to be heard on the allegations or evidence.

Article 44

Injunctions

1. The judicial authorities shall have the authority to order a party to desist from an infringement, *inter alia* to prevent the entry into the channels of commerce in their jurisdiction of imported goods that involve the infringement of an intellectual property right, immediately after customs clearance of such goods. Members are not obliged to accord such authority in respect of protected subject matter acquired or ordered by a person prior to knowing or having reasonable grounds to know that dealing in such subject matter would entail the infringement of an intellectual property right.

2. Notwithstanding the other provisions of this Part and provided that the provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with, Members may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Article 31. In other cases, the remedies under this Part shall apply or, where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available.

Article 45

Damages

1. The judicial authorities shall have the authority to order the infringer to pay the right holder damages adequate to compensate for the injury the right holder has suffered because of an infringement of that person’s intellectual property right by an infringer who knowingly, or with reasonable grounds to know, engaged in infringing activity.

2. The judicial authorities shall also have the authority to order the infringer to pay the right holder expenses, which may include appropriate attorney's fees. In appropriate cases, Members may authorize the judicial authorities to order recovery of profits and/or payment of pre-established damages even where the infringer did not knowingly, or with reasonable grounds to know, engage in infringing activity.

Article 46

Other Remedies

In order to create an effective deterrent to infringement, the judicial authorities shall have the authority to order that goods that they have found to be infringing be, without compensation of any sort, disposed of outside the channels of commerce in such a manner as to avoid any harm caused to the right holder, or, unless this would be contrary to existing constitutional requirements, destroyed. The judicial authorities shall also have the authority to order that materials and implements the predominant use of which has been in the creation of the infringing goods be, without compensation of any sort, disposed of outside the channels of commerce in such a manner as to minimize the risks of further infringements. In considering such requests, the need for proportionality between the seriousness of the infringement and the remedies ordered as well as the interests of third parties shall be taken into account. In regard to counterfeit trademark goods, the simple removal of the trademark unlawfully affixed shall not be sufficient, other than in exceptional cases, to permit release of the goods into the channels of commerce.

Article 47

Right of Information

Members may provide that the judicial authorities shall have the authority, unless this would be out of proportion to the seriousness of the infringement, to order the infringer to inform the right holder of the identity of third persons involved in the production and distribution of the infringing goods or services and of their channels of distribution.

Article 48

Indemnification of the Defendant

1. The judicial authorities shall have the authority to order a party at whose request measures were taken and who has abused enforcement procedures to provide to a party wrongfully enjoined or restrained adequate compensation for the injury suffered because of such abuse. The judicial authorities shall also have the authority to order the applicant to pay the defendant expenses, which may include appropriate attorney's fees.

2. In respect of the administration of any law pertaining to the protection or enforcement of intellectual property rights, Members shall only exempt both public authorities and officials from liability to appropriate remedial measures where actions are taken or intended in good faith in the course of the administration of that law.

Article 49

Administrative Procedures

To the extent that any civil remedy can be ordered as a result of administrative procedures on the merits of a case, such procedures shall conform to principles equivalent in substance to those set forth in this Section.

SECTION 3: PROVISIONAL MEASURES

Article 50

1. The judicial authorities shall have the authority to order prompt and effective provisional measures:

(a) to prevent an infringement of any intellectual property right from occurring, and in particular to prevent the entry into the channels of commerce in their jurisdiction of goods, including imported goods immediately after customs clearance;

(b) to preserve relevant evidence in regard to the alleged infringement.

2. The judicial authorities shall have the authority to adopt provisional measures *inaudita altera parte* where appropriate, in particular where any delay is likely to cause irreparable harm to the right holder, or where there is a demonstrable risk of evidence being destroyed.

3. The judicial authorities shall have the authority to require the applicant to provide any reasonably available evidence in order to satisfy themselves with a sufficient degree of certainty that the applicant is the right holder and that the applicant's right is being infringed or that such infringement is imminent, and to order the applicant to provide a security or equivalent assurance sufficient to protect the defendant and to prevent abuse.

4. Where provisional measures have been adopted *inaudita altera parte*, the parties affected shall be given notice, without delay after the execution of the measures at the latest. A review, including a right to be heard, shall take place upon request of the defendant with a view to deciding, within a reasonable period after the notification of the measures, whether these measures shall be modified, revoked or confirmed.

5. The applicant may be required to supply other information necessary for the identification of the goods concerned by the authority that will execute the provisional measures.

6. Without prejudice to paragraph 4, provisional measures taken on the basis of paragraphs 1 and 2 shall, upon request by the defendant, be revoked or otherwise cease to have effect, if proceedings leading to a decision on the merits of the case are not initiated within a reasonable period, to be determined by the judicial authority ordering the measures where a Member's law so permits or, in the absence of such a determination, not to exceed 20 working days or 31 calendar days, whichever is the longer.

7. Where the provisional measures are revoked or where they lapse due to any act or omission by the applicant, or where it is subsequently found that there has been no

infringement or threat of infringement of an intellectual property right, the judicial authorities shall have the authority to order the applicant, upon request of the defendant, to provide the defendant appropriate compensation for any injury caused by these measures.

8. To the extent that any provisional measure can be ordered as a result of administrative procedures, such procedures shall conform to principles equivalent in substance to those set forth in this Section.

SECTION 4: SPECIAL REQUIREMENTS RELATED TO BORDER MEASURES[12]

Article 51

Suspension of Release by Customs Authorities

Members shall, in conformity with the provisions set out below, adopt procedures[13] to enable a right holder, who has valid grounds for suspecting that the importation of counterfeit trademark or pirated copyright goods[14] may take place, to lodge an application in writing with competent authorities, administrative or judicial, for the suspension by the customs authorities of the release into free circulation of such goods. Members may enable such an application to be made in respect of goods which involve other infringements of intellectual property rights, provided that the requirements of this Section are met. Members may also provide for corresponding procedures concerning the suspension by the customs authorities of the release of infringing goods destined for exportation from their territories.

Article 52

Application

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[12] Where a Member has dismantled substantially all controls over movement of goods across its border with another Member with which it forms part of a customs union, it shall not be required to apply the provisions of this Section at that border.

[13] It is understood that there shall be no obligation to apply such procedures to imports of goods put on the market in another country by or with the consent of the right holder, or to goods in transit.

[14] For the purposes of this Agreement:

(a) "counterfeit trademark goods" shall mean any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation;

(b) "pirated copyright goods" shall mean any goods which are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation.

Any right holder initiating the procedures under Article 51 shall be required to provide adequate evidence to satisfy the competent authorities that, under the laws of the country of importation, there is *prima facie* an infringement of the right holder's intellectual property right and to supply a sufficiently detailed description of the goods to make them readily recognizable by the customs authorities. The competent authorities shall inform the applicant within a reasonable period whether they have accepted the application and, where determined by the competent authorities, the period for which the customs authorities will take action.

Article 53

Security or Equivalent Assurance

1. The competent authorities shall have the authority to require an applicant to provide a security or equivalent assurance sufficient to protect the defendant and the competent authorities and to prevent abuse. Such security or equivalent assurance shall not unreasonably deter recourse to these procedures.

2. Where pursuant to an application under this Section the release of goods involving industrial designs, patents, layout-designs or undisclosed information into free circulation has been suspended by customs authorities on the basis of a decision other than by a judicial or other independent authority, and the period provided for in Article 55 has expired without the granting of provisional relief by the duly empowered authority, and provided that all other conditions for importation have been complied with, the owner, importer, or consignee of such goods shall be entitled to their release on the posting of a security in an amount sufficient to protect the right holder for any infringement. Payment of such security shall not prejudice any other remedy available to the right holder, it being understood that the security shall be released if the right holder fails to pursue the right of action within a reasonable period of time.

Article 54

Notice of Suspension

The importer and the applicant shall be promptly notified of the suspension of the release of goods according to Article 51.

Article 55

Duration of Suspension

If, within a period not exceeding 10 working days after the applicant has been served notice of the suspension, the customs authorities have not been informed that proceedings leading to a decision on the merits of the case have been initiated by a party other than the defendant, or that the duly empowered authority has taken provisional measures prolonging the suspension of the release of the goods, the goods shall be released, provided that all other conditions for importation or exportation have been

complied with; in appropriate cases, this time-limit may be extended by another 10 working days. If proceedings leading to a decision on the merits of the case have been initiated, a review, including a right to be heard, shall take place upon request of the defendant with a view to deciding, within a reasonable period, whether these measures shall be modified, revoked or confirmed. Notwithstanding the above, where the suspension of the release of goods is carried out or continued in accordance with a provisional judicial measure, the provisions of paragraph 6 of Article 50 shall apply.

Article 56

Indemnification of the Importer and of the Owner of the Goods

Relevant authorities shall have the authority to order the applicant to pay the importer, the consignee and the owner of the goods appropriate compensation for any injury caused to them through the wrongful detention of goods or through the detention of goods released pursuant to Article 55.

Article 57

Right of Inspection and Information

Without prejudice to the protection of confidential information, Members shall provide the competent authorities the authority to give the right holder sufficient opportunity to have any goods detained by the customs authorities inspected in order to substantiate the right holder's claims. The competent authorities shall also have authority to give the importer an equivalent opportunity to have any such goods inspected. Where a positive determination has been made on the merits of a case, Members may provide the competent authorities the authority to inform the right holder of the names and addresses of the consignor, the importer and the consignee and of the quantity of the goods in question.

Article 58

Ex Officio Action

Where Members require competent authorities to act upon their own initiative and to suspend the release of goods in respect of which they have acquired *prima facie* evidence that an intellectual property right is being infringed:

(a) the competent authorities may at any time seek from the right holder any information that may assist them to exercise these powers;

(b) the importer and the right holder shall be promptly notified of the suspension. Where the importer has lodged an appeal against the suspension with the competent authorities, the suspension shall be subject to the conditions, *mutatis mutandis*, set out at Article 55;

(c) Members shall only exempt both public authorities and officials from liability to appropriate remedial measures where actions are taken or intended in good faith.

Article 59

Remedies

Without prejudice to other rights of action open to the right holder and subject to the right of the defendant to seek review by a judicial authority, competent authorities shall have the authority to order the destruction or disposal of infringing goods in accordance with the principles set out in Article 46. In regard to counterfeit trademark goods, the authorities shall not allow the re-exportation of the infringing goods in an unaltered state or subject them to a different customs procedure, other than in exceptional circumstances.

Article 60

De Minimis Imports

Members may exclude from the application of the above provisions small quantities of goods of a non-commercial nature contained in travellers' personal luggage or sent in small consignments.

SECTION 5: CRIMINAL PROCEDURES

Article 61

Members shall provide for criminal procedures and penalties to be applied at least in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale. Remedies available shall include imprisonment and/or monetary fines sufficient to provide a deterrent, consistently with the level of penalties applied for crimes of a corresponding gravity. In appropriate cases, remedies available shall also include the seizure, forfeiture and destruction of the infringing goods and of any materials and implements the predominant use of which has been in the commission of the offence. Members may provide for criminal procedures and penalties to be applied in other cases of infringement of intellectual property rights, in particular where they are committed wilfully and on a commercial scale.

PART IV

ACQUISITION AND MAINTENANCE OF INTELLECTUAL PROPERTY RIGHTS AND RELATED *INTER-PARTES* PROCEDURES

Article 62

1. Members may require, as a condition of the acquisition or maintenance of the intellectual property rights provided for under Sections 2 through 6 of Part II, compliance with reasonable procedures and formalities. Such procedures and formalities shall be consistent with the provisions of this Agreement.

2. Where the acquisition of an intellectual property right is subject to the right being granted or registered, Members shall ensure that the procedures for grant or registration, subject to compliance with the substantive conditions for acquisition of the right, permit the granting or registration of the right within a reasonable period of time so as to avoid unwarranted curtailment of the period of protection.

3. Article 4 of the Paris Convention (1967) shall apply *mutatis mutandis* to service marks.

4. Procedures concerning the acquisition or maintenance of intellectual property rights and, where a Member's law provides for such procedures, administrative revocation and *inter partes* procedures such as opposition, revocation and cancellation, shall be governed by the general principles set out in paragraphs 2 and 3 of Article 41.

5. Final administrative decisions in any of the procedures referred to under paragraph 4 shall be subject to review by a judicial or quasi-judicial authority. However, there shall be no obligation to provide an opportunity for such review of decisions in cases of unsuccessful opposition or administrative revocation, provided that the grounds for such procedures can be the subject of invalidation procedures.

PART V

DISPUTE PREVENTION AND SETTLEMENT

Article 63

Transparency

1. Laws and regulations, and final judicial decisions and administrative rulings of general application, made effective by a Member pertaining to the subject matter of this Agreement (the availability, scope, acquisition, enforcement and prevention of the abuse of intellectual property rights) shall be published, or where such publication is not practicable made publicly available, in a national language, in such a manner as to enable governments and right holders to become acquainted with them. Agreements concerning the subject matter of this Agreement which are in force between the government or a governmental agency of a Member and the government or a governmental agency of another Member shall also be published.

2. Members shall notify the laws and regulations referred to in paragraph 1 to the Council for TRIPS in order to assist that Council in its review of the operation of this

Agreement. The Council shall attempt to minimize the burden on Members in carrying out this obligation and may decide to waive the obligation to notify such laws and regulations directly to the Council if consultations with WIPO on the establishment of a common register containing these laws and regulations are successful. The Council shall also consider in this connection any action required regarding notifications pursuant to the obligations under this Agreement stemming from the provisions of Article 6*ter* of the Paris Convention (1967).

3. Each Member shall be prepared to supply, in response to a written request from another Member, information of the sort referred to in paragraph 1. A Member, having reason to believe that a specific judicial decision or administrative ruling or bilateral agreement in the area of intellectual property rights affects its rights under this Agreement, may also request in writing to be given access to or be informed in sufficient detail of such specific judicial decisions or administrative rulings or bilateral agreements.

4. Nothing in paragraphs 1, 2 and 3 shall require Members to disclose confidential information which would impede law enforcement or otherwise be contrary to the public interest or would prejudice the legitimate commercial interests of particular enterprises, public or private.

Article 64

Dispute Settlement

1. The provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied by the Dispute Settlement Understanding shall apply to consultations and the settlement of disputes under this Agreement except as otherwise specifically provided herein.

2. Subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 shall not apply to the settlement of disputes under this Agreement for a period of five years from the date of entry into force of the WTO Agreement.

3. During the time period referred to in paragraph 2, the Council for TRIPS shall examine the scope and modalities for complaints of the type provided for under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 made pursuant to this Agreement, and submit its recommendations to the Ministerial Conference for approval. Any decision of the Ministerial Conference to approve such recommendations or to extend the period in paragraph 2 shall be made only by consensus, and approved recommendations shall be effective for all Members without further formal acceptance process.

PART VI

TRANSITIONAL ARRANGEMENTS

Article 65

Transitional Arrangements

1. Subject to the provisions of paragraphs 2, 3 and 4, no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the WTO Agreement.

2. A developing country Member is entitled to delay for a further period of four years the date of application, as defined in paragraph 1, of the provisions of this Agreement other than Articles 3, 4 and 5.

3. Any other Member which is in the process of transformation from a centrally-planned into a market, free-enterprise economy and which is undertaking structural reform of its intellectual property system and facing special problems in the preparation and implementation of intellectual property laws and regulations, may also benefit from a period of delay as foreseen in paragraph 2.

4. To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.

5. A Member availing itself of a transitional period under paragraphs 1, 2, 3 or 4 shall ensure that any changes in its laws, regulations and practice made during that period do not result in a lesser degree of consistency with the provisions of this Agreement.

Article 66

Least-Developed Country Members

1. In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.

2. Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.

Article 67

Technical Cooperation

In order to facilitate the implementation of this Agreement, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country Members. Such cooperation shall include assistance in the preparation of laws and regulations on the protection and enforcement of intellectual property rights as well as on the prevention of their abuse, and shall include support regarding the establishment or reinforcement of domestic offices and agencies relevant to these matters, including the training of personnel.

PART VII

INSTITUTIONAL ARRANGEMENTS; FINAL PROVISIONS

Article 68

Council for Trade-Related Aspects of Intellectual Property Rights

The Council for TRIPS shall monitor the operation of this Agreement and, in particular, Members' compliance with their obligations hereunder, and shall afford Members the opportunity of consulting on matters relating to the trade-related aspects of intellectual property rights. It shall carry out such other responsibilities as assigned to it by the Members, and it shall, in particular, provide any assistance requested by them in the context of dispute settlement procedures. In carrying out its functions, the Council for TRIPS may consult with and seek information from any source it deems appropriate. In consultation with WIPO, the Council shall seek to establish, within one year of its first meeting, appropriate arrangements for cooperation with bodies of that Organization.

Article 69

International Cooperation

Members agree to cooperate with each other with a view to eliminating international trade in goods infringing intellectual property rights. For this purpose, they shall establish and notify contact points in their administrations and be ready to exchange information on trade in infringing goods. They shall, in particular, promote the exchange of information and cooperation between customs authorities with regard to trade in counterfeit trademark goods and pirated copyright goods.

Article 70

Protection of Existing Subject Matter

1. This Agreement does not give rise to obligations in respect of acts which occurred before the date of application of the Agreement for the Member in question.

2. Except as otherwise provided for in this Agreement, this Agreement gives rise to obligations in respect of all subject matter existing at the date of application of this Agreement for the Member in question, and which is protected in that Member on the said date, or which meets or comes subsequently to meet the criteria for protection under the terms of this Agreement. In respect of this paragraph and paragraphs 3 and 4, copyright obligations with respect to existing works shall be solely determined under Article 18 of the Berne Convention (1971), and obligations with respect to the rights of producers of phonograms and performers in existing phonograms shall be determined solely under Article 18 of the Berne Convention (1971) as made applicable under paragraph 6 of Article 14 of this Agreement.

3. There shall be no obligation to restore protection to subject matter which on the date of application of this Agreement for the Member in question has fallen into the public domain.

4. In respect of any acts in respect of specific objects embodying protected subject matter which become infringing under the terms of legislation in conformity with this Agreement, and which were commenced, or in respect of which a significant investment was made, before the date of acceptance of the WTO Agreement by that Member, any Member may provide for a limitation of the remedies available to the right holder as to the continued performance of such acts after the date of application of this Agreement for that Member. In such cases the Member shall, however, at least provide for the payment of equitable remuneration.

5. A Member is not obliged to apply the provisions of Article 11 and of paragraph 4 of Article 14 with respect to originals or copies purchased prior to the date of application of this Agreement for that Member.

6. Members shall not be required to apply Article 31, or the requirement in paragraph 1 of Article 27 that patent rights shall be enjoyable without discrimination as to the field of technology, to use without the authorization of the right holder where authorization for such use was granted by the government before the date this Agreement became known.

7. In the case of intellectual property rights for which protection is conditional upon registration, applications for protection which are pending on the date of application of this Agreement for the Member in question shall be permitted to be amended to claim any enhanced protection provided under the provisions of this Agreement. Such amendments shall not include new matter.

8. Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:

(a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;

(b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement

as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and

(c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).

9. Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member.

Article 71

Review and Amendment

1. The Council for TRIPS shall review the implementation of this Agreement after the expiration of the transitional period referred to in paragraph 2 of Article 65. The Council shall, having regard to the experience gained in its implementation, review it two years after that date, and at identical intervals thereafter. The Council may also undertake reviews in the light of any relevant new developments which might warrant modification or amendment of this Agreement.

2. Amendments merely serving the purpose of adjusting to higher levels of protection of intellectual property rights achieved, and in force, in other multilateral agreements and accepted under those agreements by all Members of the WTO may be referred to the Ministerial Conference for action in accordance with paragraph 6 of Article X of the WTO Agreement on the basis of a consensus proposal from the Council for TRIPS.

Article 72

Reservations

Reservations may not be entered in respect of any of the provisions of this Agreement without the consent of the other Members.

Article 73

Security Exceptions

Nothing in this Agreement shall be construed:

(a) to require a Member to furnish any information the disclosure of which it considers contrary to its essential security interests; or

(b) to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests;

(i) relating to fissionable materials or the materials from which they are derived;

(ii) relating to the traffic in arms, ammunition and implements of war and to such traffic in other goods and materials as is carried on directly or indirectly for the purpose of supplying a military establishment;

(iii) taken in time of war or other emergency in international relations; or

(c) to prevent a Member from taking any action in pursuance of its obligations under the United Nations Charter for the maintenance of international peace and security.