Online supplemental appendix:

Overview of selected MPP licences relative to key features discussed in the main article

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Negotiating public-health intellectual property licensing agreements to increase access to health technologies: an insider's story

Charles Gore, LLB¹, Sébastien Morin, PhD², John-Arne Røttingen, MD PhD^{3,4}, Marie Paule Kieny, PhD³

- 1. Management, Medicines Patent Pool, Geneva, Switzerland
- 2. Policy, Strategy and Market Access, Medicines Patent Pool, Geneva, Switzerland
- 3. Governance Board, Medicines Patent Pool, Geneva, Switzerland
- 4. Global Health, Norwegian Ministry of Foreign Affairs, Oslo, Norway

Corresponding author

Sébastien Morin, PhD Medicines Patent Pool Rue de Varembé 7 CH-1202 Geneva Switzerland Email: <u>smorin@mppf.ch</u>

<u>Disclaimer</u>

This appendix summarizes, in lay language, the key features of MPP licences for HIV, HCV, COVID-19, and cancer medicines. In case of any doubt, language in the individual licensing agreements prevails, and the interested reader is accordingly invited to directly refer to those specific individual licensing agreements (publicly available on MPP's website at: https://medicinespatentpool.org/progress-achievements/licences) for the exact legal language around any specific clause. Complementary country-specific patenting and licensing information is available on the MPP medicines patents and licences public database MedsPaL (www.medspal.org). The appendix information was verified as current on 28 August 2023. Information on any subsequent improvements or other changes to any of the licences presented in the appendix may be found on the corresponding MPP webpages for those licences.

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Abbreviations

AP	Ы	Active pharmaceutical ingredient
AR	RVs	Antiretrovirals
AT	TOM	Access to Oncology Medicine Coalition
DN	JDi	Drugs for Neglected Diseases initiative
EU	J	European Union
HIC	С	High-income country
LIC	С	Low-income country
LN	4IC	Low- and middle-income country
MI	C	Middle-income country
PH	IEIC	Public health emergency of international concern
PL	HIV	People living with HIV
RT	V	Ritonavir (also defined as "r" when referred to as part of a combination with lopinavir: LPV/r)
UN	ЛIС	Upper-middle-income country
US	SA	United States of America
US	5 FDA	United States Food and Drug Administration
US	S NIH	United States National Institute of Health
WI	НО	World Health Organization

Table S-1. Overview of selected MPP licences for HIV medicines

Licence	Patent holder	Indication	Population	Year	Original nominal territory (# countries)	Nominal territory expansion (# countries)	Sales outside of the nominal territory ^A	Data exclusivity waiver	Royalties	Market segmentation	Compound patent expiry ^B	Sublicensing	Grant back rights	Combinations	Technology transfer	Source
Abacavir (ABC) – Paediatrics	ViiV Healthcare	HIV treatment	Paediatric	2013	118 countries	+3 in 2014 121 countries nominally included	Sales outside the nominal territory permitted if no granted patent is being infringed, including in the case of a compulsory licence	Yes	Royalty-free	-	2010	Sublicences can be issued to qualified entities worldwide	Sublicensee to grant to ViiV and MPP a perpetual, irrevocable, worldwide, royalty free, non-exclusive licence to use improvements, improvement patents and related know-how	Sublicensees have the right to combine ABC with other ARVs and to develop new fixed- dose combinations	-	[1]
Atazanavir (ATV)	Bristol-Myers Squibb	Prevention, treatment or control of HIV and AIDS	Not specified	2013	110 countries	+12 in 2017 122 countries nominally included	Sales outside the nominal territory permitted for manufacturers that do not rely on BMS technology and if no granted patent is being infringed, including in the case of a compulsory licence	Yes	3 % royalties (not payable for paediatric formulations or for sales of adult formulations in Sub- Saharan Africa and India) Royalties to be collected by MPP and channelled to a community-based HIV organization in the country paying the royalty	-	2017	Sublicences can be issued to qualified entities worldwide	Sublicensee to grant BMS and MPP a non- exclusive, perpetual, worldwide, royalty- free licence to use any such invention and any related intellectual property	Sublicensees have the right to combine ATV with other ARVs and to develop new fixed- dose combinations	A technology transfer package is provided to all the sub-increases, but there is no obligation to use the technology	[2]
Bictegravir (BIC)	Gilead Sciences ^c	Any use that is consistent with the label approved by the US FDA or applicable national regulatory authority in the country of sale	Not specified	2017	116 countries	+1 in 2019 117 countries nominally included	Sales outside the nominal territory permitted in the case of a compulsory licence	Yes	5% royalties (not for APIs and paediatric formulations)	-	2033	Sublicences can be issued to entities based in China, India, and South Africa	Sublicensee to grant Gilead Sciences and MPP a non-exclusive, royally-free, worldwide, sublicensable licence to all improvements, methods, modifications, and other know-how developed by or on behalf of licensee and relating to API or a product	Sublicensees have the right to combine BIC with other ARVs and to develop suitable new fixed-dose combinations	All Indian and South- African sub-licensees benefit from a one- time technology transfer	[3]
Cabotegravir (CAB)	ViiV Healthcare	HIV prevention	Not specified	2022	90 countries	90 countries nominally included	Sales outside the nominal territory permitted if no granted patent is being infringed, including in the case of a compulsory licence	Yes	5% royalties for 10 countries where ViiV holds patent rights: Algeria, Egypt, India, Indonesia, Kyrgyzstan, Morocco, Philippines, Tajikistan, Ukraine, Vietnam	Limitation to the public market only for 10 countries: Algeria, Egypt, India, Indonesia, Kyrgyzstan, Morocco, Philippines, Tajikistan, Ukraine, Vietnam	2031	Sublicences can be issued to any qualified entity worldwide The number of sublicensees is limited to three, with a possibility to have additional sublicensees if the evidence demonstrates a public health need for it	Sublicensee to grant Vii V and MPP a perpetual, irrevocable, worldwide, royalty- free, non-exclusive licence to use improvements, improvements, and related know-how		A technology transfer package will be provided by VitV Healthcare to each sublicences eas defined in a separate agreement ^D	[4]

Licence	Patent holder	Indication	Population	Year	Original nominal territory (# countries)	Nominal territory expansion (# countries)	Sales outside of the nominal territory ^A	Data exclusivity waiver	Royalties	Market segmentation	Compound patent expiry ^B	Sublicensing	Grant back rights	Combinations	Technology transfer	Source
Cobicistat (COBI)	Gilead Sciences ^c	Any use that is consistent with the label approved by the US FDA or applicable national regulatory authority in the country of sale	Not specified	2011	112 countries	+4 in 2017 +1 in 2019 117 countries nominally included	Sales outside the nominal territory permitted in the case of a compulsory licence	Yes	5% royalties (not for APIs and paediatric formulations)	-	2028	Sublicences can be issued to entities based in China, India, and South Africa	Sublicensee to grant Gilead Sciences and MPP a non-exclusive, royalty-free, worldwide, sublicensable licence to all improvements, methods, modifications, and other know-how developed by or on behalf of licensee and relating to API or a product	Sublicensees have the right to combine COBI with other ARVs and to develop suitable new Krked- dose combinations	All Indian and South- African sub-licensees benefit from a one- time technology transfer	[5]
Darunavir (DRV) ^E	US NIH	Treatment and prevention of medical conditions affecting humans	Not specified	2010	137 countries (granted for all LMICs)	- 137 countries nominally included	-	-	Royalty-free	-	2013/2014	Sublicences can be issued to qualified entities worldwide	-	-	-	[6]
Dolutegravir (DTG) – Adults	ViiV Healthcare	HIV treatment	Adults	2014	73 countries	+19 in 2016 +2 in 2018 +1 in 2020 95 countries nominally included	Sales outside the nominal territory permitted if no granted patent is being infringent including in the case of a compulsory licence	Yes	Variable royalties depending on country: 5% for India, Moldova, Philippines, Vietnam 7.5% for Algeria, Armenia, Egypt, Indonesia, Mongolia, Morocco, Tunsia, Ukraine 10% for Turkmenistan	Limitation to the public market only for 13 countries: Algeria, Armenia, Egypt, Indonesia, Indonesia, Moldova, Moldova, Mongolia, Morocco, Philippines, Tuntsia, Turkmenistan, Ukraine, Vietnam	2026	Sublicences can be issued to qualified entities worldwide	Sublicensee to grant ViiV and MPP a perpetual, irrevocable, worldwide, royalty- free, non-exclusive licence to use improvements, improvement, patents and related know-how	Sublicensees have the right to combine DTG with other ARVs and to develop suitable new fixed-dose combinations		[7]
Dolutegravir (DTG) – 4 UMICs	ViiV Healthcare	HIV treatment	Adults	2020	4 countries	4 countries nominally included	Sales outside the nominal territory permitted if no granted patent is being infringed, including in the case of a compulsory licence	Yes	Tiered per-pack royalty rates (kept confidential) based on percentage of PLHIV treated with DTG ^F	Limitation to the public market only for 4 countries: Azerbaijan, Belarus, Kazakhstan, Malaysia	2026	Sublicences can be issued to qualified entities worldwide The number of sublicensees is limited to three due to market size	Sublicensee to grant ViiV and MPP a perpetual, irrevocable, worldwide, royalty- free, non-exclusive licence to use improvements, improvement patents and related know-how	Sublicensees have the right to combine DTG with other ARVs and to develop suitable new fixed-dose combinations	-	[8]
Dolutegravir (DTG) – Paediatrics	ViiV Healthcare	HIV treatment	Paediatric	2014	123 countries	+2 in 2020 125 countries nominally included	Sales outside the nominal territory permitted if no granted patent is being infringed, including in the case of a compulsory licence	Yes	Royalty-free	-	2026	Sublicences can be issued to any qualified entity worldwide	Sublicensee to grant ViiV and MPP a perpetual, irrevocable, worldwide, royalty- free, non-exclusive licence to use improvements, improvements, and related know-how	Sublicensees have the right to combine DTG with other ARVs and to develop suitable new fixed-dose combinations	-	[9]

Licence		Indication	Population	Year	Original nominal territory (# countries)	Nominal territory expansion (# countries)	Sales outside of the nominal territory ^A	Data exclusivity waiver	Royalties	Market segmentation	Compound patent expiry ^B	Sublicensing	Grant back rights	Combinations	Technology transfer	
Elvitegravir (EVG)	Gilead Sciences ^c	Any use that is consistent with the label approved by the US FDA or applicable national regulatory authority in the country of sale	Not specified	2011	100 countries	+9 in 2017 109 countries nominally included	Sales outside the nominal territory permitted in the case of a compulsory licence	Yes	5% royalties (not for APIs and paediatric formulations)	-	2023	Sublicences can be issued to entities based in China, India, and South Africa	Sublicensee to grant Gilead Sciences and MPP a non-exclusive, royalty-free, worldwide, sublicensable licence to all improvements, methods, modifications, and other know-how developed by or on behalf of licensee and relating to API or a product	Sublicensees have the right to combine EVG with other ARVs and to develop suitable new fixed-dose combinations	All Indian and South- Arrican sub-licensees benefit from a one- time technology transfer	[10]
Emtricitabine (FTC)	Gilead Sciences ^c	Any use that is consistent with the label approved by the US FDA or applicable national regulatory authority in the country of sale	Not specified	2011	112 countries	+4 in 2017 +1 in 2019 117 countries nominally included	Sales outside the nominal territory permitted in the case of a compulsory licence	Yes	Royalty-free	-	2012	Sublicences can be issued to entities based in China, India, and South Africa	Sublicensee to grant Gilead Sciences and MPP a non-exclusive, royalty-free, worldwide, sublicensable licence to all improvements, methods, modifications, and other know-how developed by or on behal for licensee and relating to API or a product	Sublicensees have the right to combine FTC with other ARVs and to develop suitable new fixed-dose combinations	All Indian and South- African sub-licensees benefit from a one- time technology transfer	[11]
Lopinavir / ritonavir (LPV/r) – Adults	AbbVie	HIV treatment	Adult	2015	54 countries	Now worldwide (patents not enforced since 2020)	Sales outside the nominal territory permitted if no granted patent is being infringed, including in the case of a compulsory licence	Yes	Royalty-free	-	2016/2013 (in addition to key secondary patent on heat-stable formulation until 2024)	Sublicences can be issued to any qualified entity worldwide	-	Sublicensees have the right to combine LPV or RTV with other ARVs and to develop suitable new fixed- dose combinations	-	[12]
Lopinavir / ritonavir (LPV/r) – Paediatrics	AbbVie	HIV treatment or prevention	Paediatric HIV treatment or prevention	2014	102 countries	Now worldwide (patents not enforced since 2020)	Sales outside the nominal territory permitted if no granted patent is being infringed, including in the case of a compulsory licence	Yes	Royalty-free	-	2016/2013 (in addition to key secondary patent on heat-stable formulation until 2024)	Sublicences can be issued to any qualified entity worldwide	-	Sublicensees have the right to combine LPV or RTV with other ARVs and to develop suitable new fixed- dose combinations	-	[13]
Raltegravir (RAL) – Paediatrics	MSD	HIV treatment	Children under 12 years of age	2015	92 countries	92 countries nominally included	Sales outside the nominal territory permitted if no granted patent is being infringed, including in the case of a compulsory licence	Yes	Royalty-free	-	2024	Sublicences can be issued to any qualified entity worldwide	Sublicensee to grant MSD and MPP a royalty-free, non- exclusive, sublicensable licence to any patented improvement. Merek is also granted a right of first refusal to negotiate a new formulation outside the territory	Sublicensees have the right to combine RAL with other ARVs and to develop suitable new fixed-dose combinations	-	[14]

Licence	Patent holder	Indication	Population	Year		expansion (# countries)	Sales outside of the nominal territory ^A	Data exclusivity waiver	Royalties	Market segmentation	Compound patent expiry ^B	Sublicensing	Grant back rights	Combinations	Technology transfer	Source
Tenofovir alafenamide (TAF)	Gilead Sciences ^c	Any use that is consistent with the label approved by the US FDA or applicable national regulatory authority in the country of sale	Not specified	2014	112 countries		Sales outside the nominal territory permitted in the case of a compulsory licence	Yes	5% royalties (not for APIs and paediatric formulations)	-	2021	Sublicences can be issued to entities based in China, India, and South Africa	Sublicensee to grant Gilead Sciences and MPP a non-exclusive, royalty-free, worldwide, sublicensable licence to all improvements, methods, modifications, and other know-how developed by or on behalf of licensee and relating to API or a product	Sublicensees have the right to combine TAF with other AFVS and to develop suitable new fixed-dose combinations	All Indian and South- African sub-licensees benefit from a one- time technology transfer	[15]
Tenofovir disoproxil fumarate (TDF) ^G	Gilead Sciences ^c	Any use that is consistent with the label approved by the US FDA or applicable national regulatory authority in the country of sale	Adult and paediatric (with sales of paediatric formulations prohibited above 12 years of age)	2011	112 countries		Sales outside the nominal territory permitted in the case of a compulsory licence	Yes	3-5% royalties (not for APIs and paediatric formulations)	-	2017	Sublicences can be issued to entities based in China, India, and South Africa	Sublicensee to grant Gilead Sciences and MPP a non-exclusive, royalty-free, worldwide, sublicensable licence to all improvements, methods, modifications, and other know-how developed by or on behalf of licensee and relating to API or a product	Sublicensees have the right to combine TDF with other ARVs and to develop suitable new fixed-dose combinations	All Indian and South- African sub-licensees benefit from a one- time technology transfer	[16]

A. Information on the effective allowed territory for MPP-licensed products is available on MPP's Access to Medicines Tracker's Interactive Map on the MPP website at: <u>https://medicinespatentpool.org/progress-achievements/access-to-medicines-tracker</u>.

B. Compound patent expiry dates shown in this document are generally 20 years from the filing of the patent application. Exact country-specific dates of expiry may vary as a result of differences in national patent laws or the existence of patent term extensions in some jurisdictions. For country-specific patent information (including for any secondary patents), the reader is invited to consult the MPP medicines patents and licences public database MedsPaL at: www.medspal.org.

C. All the HIV medicines licensed by Gilead Sciences to MPP are part of the same overall licence and benefit from the same overall terms and conditions.

D. The terms of a separate agreement defining a technology transfer package to be provided by ViiV Healthcare to each sublicensee for CAB are currently under discussion.

E. This MPP-US NIH licence does not cover all patents for DRV (and in 2015 MPP also collaborated with patent holder Janssen in expanding its commitment not to enforce patents on paediatric darunavir – see https://medicinespatentpool.org/news-publications-post/the-medicines-patent-pool-on-janssens-extension-of-its-access-policy-for-paediatric-medicine-darunavir).

F. The tiered royalty rates related to the licence for DTG for 4 UMICs are kept confidential. This is the sole exception to transparency in any MPP licence, and in its November 2020 resolution the MPP Governance Board reiterated "MPP's continued commitment to transparency" (see https://medicinespatentpool.org/uploads/2020/04/Board-Decision_UMIC-DTG-Licence November 2020 resolution the MPP Governance Board reiterated "MPP's continued commitment to transparency" (see https://medicinespatentpool.org/uploads/2020/04/Board-Decision_UMIC-DTG-Licence November 2020 resolution the MPP Governance Board reiterated "MPP's continued commitment to transparency" (see https://medicinespatentpool.org/uploads/2020/04/Board-Decision_UMIC-DTG-Licence November 2020 resolution the MPP Governance Board reiterated "MPP's continued commitment to transparency" (see

G. Similarly to other MPP licences, the MPP-Gilead Sciences licence (that covers all HIV medicines licensed by Gilead Sciences to MPP, including TDF ^C) allows licensees the right to terminate the agreement at any time on a product-by-product basis. Four companies have taken that overall licence and terminate the TDF part, allowing them to supply additional countries in which TDF was not patented.

Table S-2. Overview of selected MPP licences for HCV medicines

Licence	Patent holder	Indication	Population	Year	territory	territory	Sales outside the nominal territory ^A	Data exclusivity waiver	Royalties	Market segmentation	Compound patent expiry ^B	Sublicensing	Grant back rights	Combinations	Technology transfer	Source
Daclatasvir (DAC)	Bristol-Myers Squibb	HCV treatment	Not specified	2015	112 countries		Sales outside the nominal territory permitted for manufacturers that do not rely on BMS technology if no granted patent is being infringed, including in the case of a compulsory licence	Yes	Royalty-free	-	2027 1	issued to qualified entities worldwide	Sublicensee to grant BMS and MPP a non- exclusive, perpetual, worldwide, royalty- free licence to use any invention and related intellectual property	Sublicensees have the right to combine DAC with other drugs and to develop new fixed- dose combinations	A technology transfer package is provided to all the sublicensees, but there is no obligation to use the technology Information necessary for registration is also provided	[17]
Glecaprevir / pibrentasvir (G/P)	AbbVie	HCV treatment	Not specified	2018	95 countries	96 countries	Sales outside the nominal territory permitted if no granted patent is being infringed, including in the case of a compulsory licence	Yes	Royalty-free	-	2031	issued to any qualified	Sublicensee to grant to AbbVie for any new G/P formulation the right to purchase or to license: a sole right for USA and EU, and/or a non-exclusive right for other countries	-	AbbVie to provide, upon MPP request, a copy of clinical data and all non- commercial and non- manufacturing documents to facilitate product registration	[18]
Ravidasvir (RAV) ^H	Pharco	HCV treatment	Not specified	2017	19 countries	19 countries	Sales outside the nominal territory permitted if no granted patent is being infringed, including in the case of a compulsory licence	Yes	4% royalties for sales in LICs, 7% royalties for sales in MICs, and 12% royalties for sales in HICs	-	2029	Sublicences can be issued to any qualified entity worldwide	Sublicensee to grant Pharco and MPP a royalty-free, non- exclusive licence for patented improvements, with possibility for Pharco to sublicence to Presidio	-	-	[19]

H. This MPP-Pharco licence for RAV expands the geographic scope of the 2016 Presidio-DNDi licence (which covers 128 countries, see https://dndi.org/press-releases/2016/dndi-pharco-hepc-malaysia-thailand), extending coverage to several LMICs that were not included in that other licence.

I. Marketing authorisations and patents for daclatasvir were allowed to lapse in at least 31 countries in 2020-2021.

Table S-3. Overview of selected MPP licences for COVID-19 medicines

Licence	Patent holder	Indication	Population	Year	Original nominal territory (# countries)	Nominal territory expansion (# countries)	Sales outside the nominal territory ^A	Data exclusivity waiver	Royalties	Market segmentation	Compound patent expiry ^B	Sublicensing	Grant back rights	Combinations	Technology transfer	Source
Ensirelvir fumarie acid (ENS)	Shionogi	Treatment and/or prevention of COVID-19	Not specified	2022	117 countries	- 117 countries nominally included	Sales outside the nominal territory permitted for manufacturers that do not rely on Shionogi licensed know-how and confidential information if no patent is being infringed, including in the case of a compulsory licence	Yes	Variable Royalty-free during the WHO PHEIC After the WHO PHEIC ends: 5% for sales to governmental authorities or public purchasers and 10% of net sales for commercial entities (except for sales in LICs or for manufacture and sales in countries within the licensed territory where the product is not patented and does not benefit from regulatory exclusivity)		2030	Sublicences can be issued to any qualified entity worldwide	For COVID-19: Sublicensee to grant Shionogi and MPP a perpetual, irrevocable, worldwide, non- exclusive, transferable, and fully paid-up licence, with the right to grant sublicences through multiple titers, under any improvements <u>Outside COVID-19</u> Sublicensee to grant Shionogi and MPP a non-exclusive and royalty-free licence, or a sole licence for a fee to be negotiated		A technical pack is included in the scope of the licence, at the sublicensee's request	[20]
Molnupiravir (MOL)	MSD	Treatment of COVID-19	Not specified	2021	105 countries	+1 in 2022 106 countries nominally included	Sales outside the nominal territory permitted for manufacturers that do not rely on MSD know-how if no patent is being infringed, including in the case of a compulsory licence	Yes	Variable Royalty-free during the WHO PHEIC (except for sales to the private sector in South Africa and the public market in Thailand where royalties are also due during the WHO PHEIC) After the WHO PHEIC ends: 5% for sales to governmental authorities governmental authorities commercial entities	Limitation to the public market only for one country: Thailand	2038	Sublicences can be issued to any qualified entity worldwide	For COVID-19 Sublicensec to grant MSD and MPP a perpetual, irrevocable, worldwide, non- exclusive, transferable, and fully paid-up licence, with the right to grant sublicences through multiple tiers, under any improvements <u>Outside COVID-19</u> Sublicensee to grant MSD and MPP a non- exclusive and royalty- free licence, or a sole licence for a fee to be negotiated	-	A technical pack is included in the scope of the licence, at the sublicensee's request	[21]
Nirmatrelvir (NIR)	Pfizer	Treatment and/or prevention of COVID-19	Not specified	2021	95 countries	 95 countries nominally included	Sales outside the nominal territory permitted for manufacturers that do not rely on Pfizer licensed know-how and confidential information if no patent or any other intellectual property rights of Pfizer is being infringed, including in the case of a compulsory licence	Yes	Variable Royalty-free during the WHO PHEIC After the WHO PHEIC ends: 5% for sales to governmental authorities or public purchasers and 10% of net sales for commercial entities (except for sales in LICs or for manufacture and sales in countries within the licensed territory where the product is not patented and does not benefit from regulatory exclusivity)	Limitation to the public market only for one country: South Africa	2041	Sublicences can be issued to any qualified entity worldwide	For COVID-19 Sublicensee to grant Pfizer and MPP a perpetual, irrevocable, worldwide, non- exclusive, transferable, and fully paid-up licence, with the right to grant sublicences through multiple tiers, under any improvements <u>Outside COVID-19</u> Sublicensee to grant Pfizer and MPP a non- exclusive and royalty- free licence, or a sole licence for a fee to be negotiated	The licence is for nimatrelvir co-packaged and co-administered with ritonavir	A technical pack is included in the scope of the licence, at the sublicensee's request	[22]

Table S-4. Overview of selected MPP licences for cancer medicines

Licence	Patent holder	Indication	Population		Original nominal territory (# countries)	Nominal territory expansion (# countries)	nominal territory ^A	exclusivity waiver		Market segmentation	patent expiry ^B		Grant back rights	Combinations	Technology transfer	Source
Nilotinib		Any approved use (usually chronic myeloid leukaemia)	Adult and paediatric (above 1 year of age)	2022	44 countries	44 countries			5% royalties payable to ATOM, for sales in a country with valid patents	•	2023	manufacturing in:	Sublicensee to grant Novartis and MPP a perpetual, irrevocable, worldwide, royalty- free, fully paid-up, non-exclusive licence to use any improvement, improvement patent and related know-how		-	[23]

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