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### MPP COVID-19 Antiviral Medicines Licenses – Licensed Territories, Supply Options for Excluded Territories, and Supply Barriers Arising from Trade-Secret Transfer

Brook K. Baker

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#### MPP COVID-19 Antiviral Medicines Licenses – Licensed Territories, Supply Options for Excluded Territories, and Supply Barriers Arising from Trade-Secret Transfer Prof. Brook K. Baker, Oct. 11, 2023

#### Licensed and Unlicensed MPP Territories and Patent Status of Covid Antivirals

**Table 1** below lists low- and middle-income countries (LMICs), their inclusion/exclusion in Medicines Patent Pool licenses with Merck for molnupiravir, Pfizer for nirmatrelvir, and Shionogi for ensitrelvir fumaric acid. The MedsPaL **patent status** for each antiviral is briefly shown in the far-right column (NF=not filed; F=filed; G=granted; W=withdrawn; O=opposed).

Twenty countries/territories highlighted in PINK are currently excluded from all three MPP covid antiviral licenses licensed territories. Twenty-eight countries/territories highlighted in YELLOW are included in some MPP covid antiviral licenses territories but excluded from others. PINK and YELLOW countries facing territorial exclusions for molnupiravir may have options to source from Merck/MPP licensees that have not or other producers as described further below.

- If the territorially excluded PINK and YELLOW country's patent status is highlighted in GREEN that means that there is apparently no blocking patent preventing that antiviral from being manufactured locally. Green also means that antivirals can be imported from abroad without any import-access compulsory license being required. Suppliers from other countries are authorized to export to green/patent-free countries if:
  - (1) they are MPP licensed, WHO prequalified or emergency use approved by a stringent regulatory authority, and their manufacture and export would not infringed on any patents or patent applications in exporting country or the use of any Confidential Information supplied to MPP licensees or the misappropriation of confidential know-how.
    - Tables 3 identify licensees that have taken tech know-how packages and are thus excluded from exporting outside the territories while Table 4 identifies companies that have received WHO prequalification.
    - Whereas three molnupiravir licensees (Hetero, Dr. Reddy, Emcure) are categorically eligible to export outside the market if CL or no patent conditions are satisfied, Hetero, the only WHO prequalified nirmatrelvir licensee cannot export outside the territory under any condition.
  - (2) they are not MPP licensed but are not otherwise patent blocked from manufacturing, selling, and exporting, or
  - (3) they are not MPP-licensed and a compulsory license has been issued in the country of manufacture and export and the quantities exported would not otherwise violate national law or Articles 31, 31bis, or arguably Article 30 of the TRIPS Agreement.
- If the territorially excluded PINK and YELLOW country's patent status is highlighted in RED that means that there has been a patent granted or a patent application still pending. This means that the country will not be able to access the antiviral without issuing a compulsory license that permits local production or importation or both. As discussed above, qualified MPP licensees will be able to produce and sell and/or produce and export the antiviral if a proper compulsory license to do so has been issued in the patent-blocked,

excluded **PINK** and **YELLOW** country, <u>but only if the licensee has not taken a tech know-how package</u> (Pfizer-MPP Agreement, para. 2.4; MSD-MPP Sub-License Agreement, para. 2.20; Shionogi-MPP Agreement, para. 2.4). (*Unfortunately, as discussed above, Hetero, the single, WHO prequalified MPP-licensed producer of nirmatrelvir did take a tech know-how packet and cannot sell domestically or export to excluded countries.*)

- However, when authorizing an MPP licensee via a CL where no tech know-how package has been taken, a RED patent status country only needs to issue a local production compulsory license (for domestic production and use) or an import compulsory license, as all three relevant MPP licenses authorize supply within or to countries that have issued a compulsory license in the absence of a tech know-how package. This provision is important because it allows manufacture and distribution even if a compulsory license has not been issued in the exporting country. Moreover, there are no quantity restrictions as TRIPS Article 31(f) and Article 31*bis* do not apply.
- In addition, territorially excluded PINK and YELLOW countries that are patent-blocked could issue compulsory licenses to non-MPP licensees, but that might require compulsory licenses to be issued in the country of production/export and in the country of import in compliance with national law in both countries and with TRIPS. Regular compulsory licenses under Article 31 for export will normally be able to export only non-predominant quantities to all importing countries. Competition-based licenses under Art. 31(k), in contrast, allow export of unlimited quantities. Quantity-specific compulsory licenses can be issued pursuant to Article 31 bis procedures if the exporting country's law provides for such licenses and as long as stringent notice and product differentiation/anti-diversion rules are followed.
- The patent status on covid antivirals in some countries is marked in GREY. Here the patent status is unknown (not disclosed on the MedsPaL database or in the case of ensitrelvir the ultimate patent status is not yet known because certain PCT applications at WIPO have not yet entered the national stage.

It is important to note that the patent status in **Table 1** is as of June 26, 2023, and some of the information, especially concerning pending and granted patents may need to be updated over time. It is also possible that Pfizer, Merck, and Shionogi could file addition product and process patents on their COVID-19 antivirals. The take-away message from Table 1 is that territorially excluded countries have easy-to-use CL procedures to source covid antivirals even if they are excluded from existing MPP licenses, though those rights will be restricted where particular licensees have taken tech know-how packages from the licensors.

**Table 2** below lists the licensed territories in the three covid antiviral licenses. These lists should also be reviewed and updated over time as MPP licensees have, in the past, expanded licensed territories on several occasions. **Table 3** below lists MPP licensees that have taken tech knowhow package from Merck and Pfizer, and thus cannot produce finished pharmaceutical product for domestic use or export to an importing country outside the listed territory. **Table 4** lists the WHO prequalification and national regulatory coverage of MPP licensees.

LMICs	Molnupiravir	Nirmatrelvir	Ensitrelvir	Patents		
(OECD list)	Licensed Terr.	Licensed Terr.	Licensed Terr.	м.	N.	E.*
Afghanistan	LT	LT	LT	NF	NF	
Albania				G	G	F
Algeria	LT	LT	LT	F	F	-
Angola	LT	LT	LT	NF	NF	
Argentina				F	F	
Armenia		LT	LT	<mark>F</mark>		
<mark>Azerbaijan</mark>			LT	<mark>F</mark>	F	
Bangladesh	LT	LT	LT	NF	F	
<mark>Belarus</mark>				F		?
Belize	LT	LT	LT	F	NF	
Benin	LT	LT	LT	NF	F	
Bhutan	LT	LT	LT	NF	NF	
Bolivia	LT	LT	LT	NF	F	
<mark>Bosnia and</mark>				W	G	W?
Herzegovina						
Botswana	LT	LT	LT	F	F	
Brazil				F	E	W?
Burkina Faso	LT	LT	LT	NF	F	
Burundi	LT	LT	LT	NF	NF	
Cabo Verde	LT	LT	LT	NF	NF	
Cambodia	LT	LT	LT	WNF	G	
Cameroon	LT	LT	LT	NF	F	
Central African	LT	LT	LT	NF	F	
Republic						
Chad	LT	LT	LT	NF	F	
China (People's				F	E	G
Republic of)					_	
<mark>Colombia</mark>				F	F/O	
Comoros	LT	LT	LT	NF	F	- I
Democratic	LT	LT	LT	NF	NF	
Republic of						
Congo						
Congo	LT	LT	LT	NF	F	
Costa Rica			LT	F	F	
Côte d'Ivoire	LT	LT	LT	NF	F	
<mark>Cuba</mark>	LT		LT	NF	F	
Djibouti	LT	LT	LT	NF	NF	
Dominica	LT		LT	NF	NF	
<mark>Dominican</mark>			LT	F	F	
Republic						

 Table 1: Country List of MPP's Covid Antiviral Territorial Coverage and Patent Status

<b>Ecuador</b>			LT	F	F	
Egypt	LT	LT	LT	F	F	
El Salvador	LT	LT	LT	F	F	
Equatorial	LT	LT	LT	NF	F	
Guinea					-	
Eritrea	LT	LT	LT	NF	NF	
Eswatini	LT	LT	LT	F	F	
Ethiopia	LT	LT	LT	NF	NF	
Fiji	LT		LT	?	?	
Gabon	LT	LT	LT	NF	F	
Gambia	LT	LT	LT	F	F	
Georgia	LT	LT	LT	F	F	
Ghana	LT	LT	LT	F	F	
Grenada	LT		LT	NF	?	
Guatemala	LT	LT	LT	F	F	
Guinea	LT	LT	LT	NF	F	
Guinea-Bissau	LT	LT	LT	NF	F	
<mark>Guyana</mark>	LT		LT	NF	?	
Haiti	LT	LT	LT	NF	NF	
Honduras	LT	LT	LT	NF	F	
India	LT	LT	LT	F	F	G
Indonesia	LT	LT	LT	F/O	F	G
Iran	LT	LT	LT	F	NF	
Iraq	LT		LT	F	NF	
Jamaica	LT		LT	NF	NF	
Jordan		LT	LT	F	NF	
Kazakhstan			LT	F	F	
Kenya	LT	LT	LT	F	F	
, Kiribati	LT	LT	LT	F	NF	
Democratic	LT	LT	LT	NF	NF	
People's						
Republic of						
Korea						
Kosovo		LT	LT	NF	F	
Kyrgyzstan		LT	LT		F	
Lao People's	LT	LT	LT	NF	NF	
Democratic						
Republic						
<mark>Lebanon</mark>				G	F	
Lesotho	LT	LT	LT	F	F	
Liberia	LT	LT	LT	F	F	
<mark>Libya</mark>	LT		LT	NF	NF	
North				G	G	WE
<mark>Macedonia</mark>				-	_	-

Madagascar	LT	LT	LT	NF	NF	
Malawi	LT	LT	LT	F	F	
Malaysia				Ē	G	?
Maldives	LT		LT	NF	NF	
Mali	LT	LT	LT	NF	F	
Marshall	LT		LT	NF	NF	
Islands						
Mauritania	LT	LT	LT	NF	F	
Mauritius	LT		LT	NF	NF	
Mexico				E	F	G
Micronesia	LT	LT	LT	NF	NF	
Moldova	LT	LT	LT	W	G	
Mongolia	LT	LT	LT	F	F	
Montenegro						?
Montserrat				₩ ?	G ? G	? ?
Morocco	LT	LT	LT	W	G	
Mozambique	LT	LT	LT	F	F	
Myanmar	LT	LT	LT	NF	NF	
Namibia	LT	LT	LT	F	F	
Nauru				NF	?	?
Nepal	LT	LT	LT	NF	NF	
Nicaragua	LT	LT	LT	F	F	
Niger	LT	LT	LT	NF	F	
Nigeria	LT	LT	LT	G	F	
Niue				2	?	?
Pakistan	LT	LT	LT	? F	F	•
Panama						?
Papua New	LT	LT	LT	NF	G F	
Guinea						
Paraguay	LT		LT	NF	E	
Peru			LT		F	
Philippines	LT	LT	LT	F	F	F
Rwanda	LT	LT	LT	F	F	
Saint Helena				?	?	?
Samoa	LT	LT	LT	NF	NF	
São Tomé and	LT	LT	LT	NF	F	
Príncipe						
Senegal	LT	LT	LT	NF	F	
Serbia				G	G	WF
[Seychelles]			LT	G	NF	
Sierra Leone	LT	LT	LT	F	F	
Solomon	LT	LT	LT	?	?	
Islands				·	.	
Somalia	LT	LT	LT	NF	NF	
Somuna		<b>-</b> '			111	

South Africa	LT	LT (public sector)	LT	G	G	
South Sudan	LT	LT	LT	NF	NF	
Sri Lanka	LT	LT	LT	F	F	
<mark>Saint Lucia</mark>	LT		LT	?	?	
Saint Vincent			LT	NF	NF	
and the						
<mark>Grenadines</mark>						
Sudan	LT	LT	LT	F	F	
<mark>Suriname</mark>	LT		LT	NF	NF	
Syrian Arab	LT	LT	LT	NF	NF	
Republic						
Tajikistan	LT	LT	LT	F	F	
Tanzania	LT	LT	LT	F	F	
<mark>Thailand</mark>	LT (public sector)			F	F	WF
Timor-Leste	LT	LT	LT	NF	NF	
Тодо	LT	LT	LT	NF	F	
<mark>Tokelau</mark>				?	?	?
Tonga	LT	LT	LT	NF	NF	
Tunisia	LT	LT	LT	WNF	G	
<mark>Turkey</mark>				FG	G	G/F
Turkmenistan						?
Tuvalu	LT		LT	NF	NF	
Uganda	LT	LT	LT	F	F	
Ukraine	LT	LT	LT	F	F	
Uzbekistan	LT	LT	LT	NF	F	
Vanuatu	LT	LT	LT	NF	NF	
Venezuela	LT	LT	LT	F	F	
Vietnam	LT	LT	LT	F	F	
Wallis and				F ?	?	?
<mark>Futuna</mark>						
West Bank and		LT	LT	NF	NF	
<mark>Gaza Strip</mark>						
Yemen	LT	LT	LT	NF	NF	
Zambia	LT	LT	LT	NF	F	
Zimbabwe	LT	LT	LT	F	F	

\*Note: it is not possible to accurately assess the likely patent status of Shionogi's ensitrely fumaric acid since it has pending applications to WIPO via the Patent Cooperation Treaty applications that have not yet entered the national stage.

#### Table 2: MPP COVID-19 Antiviral Licenses – Included Territories

#### NIRMATRELVIR

Afghanistan, Algeria, Angola, Armenia, Bangladesh, Belize, Benin, Bhutan, Bolivia (Plurinational State of), Botswana, Burkina Faso, Burundi, Cabo Verde, Cambodia, Cameroon, Central African Republic, Chad, Comoros, Congo, democratic Republic of the, Congo, Côte d'Ivoire, Djibouti, Egypt, El Salvador, Equatorial Guinea, Eritrea, Eswatini, Ethiopia, Gabon, Gambia (the), Georgia, Ghana, Guatemala, Guinea, Guinea-Bissau, Haiti, Honduras, India, Indonesia, Iran (Islamic Republic of), Jordan, Kenya, Kiribati, Korea (Democratic People's Republic of), Kosovo, Kyrgyzstan, Lao People's Democratic Republic (the), Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Micronesia (Federated States of), Moldova, Republic of, Mongolia, Morocco, Mozambique, Myanmar, Namibia, Nepal, Nicaragua, Niger, Nigeria, Pakistan, Papua New Guinea, Philippines, Rwanda, Samoa, Sao Tome and Principe, Senegal, Sierra Leone, Solomon Islands, Somalia, South Africa, South Sudan, Sri Lanka, State of Palestine, Sudan, Syrian Arab Republic, Tajikistan, Tanzania, United Republic of, Timor-Leste, Togo, Tonga, Tunisia, Uganda, Ukraine, Uzbekistan, Vanuatu, Venezuela (Bolivarian Republic of), Viet Nam, Yemen, Zambia, Zimbabwe

#### MOLNUPIRAVIR

Afghanistan, Algeria, Angola, Bangladesh, Belize, Benin, Bhutan, Bolivia (Plurinational State of), Botswana, Burkina Faso, Burundi, Cabo Verde, Cambodia, Cameroon, Central African Republic, Chad, Comoros, Congo, Congo, democratic Republic of the, Côte d'Ivoire, Cuba, Djibouti, Dominica, Egypt, El Salvador, Equatorial Guinea, Eritrea, Eswatini, Ethiopia, Fiji, Gabon, Gambia (the), Ghana, Grenada, Guatemala, Guinea, Guinea-Bissau, Guyana, Haiti, Honduras, India, Indonesia, Iran (Islamic Republic of), Iraq, Jamaica, Kenya, Kiribati, Korea (Democratic People's Republic of), Lao People's Democratic Republic (the), Lesotho, Liberia, Libya, Madagascar, Malawi, Maldives, Mali, Marshall Islands, Mauritania, Mauritius, Micronesia (Federated States of), Moldova, Republic of, Mongolia, Morocco, Mozambique, Myanmar, Namibia, Nepal, Nicaragua, Niger, Nigeria, Pakistan, Papua New Guinea, Paraguay, Philippines, Rwanda, Saint Lucia, Saint Vincent and the Grenadines, Samoa, Sao Tome and Principe, Senegal, Seychelles, Sierra Leone, Solomon Islands, Somalia, South Africa, South Sudan, Sri Lanka, Sudan, Suriname, Syrian Arab Republic, Tajikistan, Tanzania, United Republic of, Timor-Leste, Togo, Tonga, Tunisia, Tuvalu, Uganda, Uzbekistan, Vanuatu, Venezuela (Bolivarian Republic of), Viet Nam, Yemen, Zambia, Zimbabwe, Thailand

#### ENSITRELVIR FUMARIC ACID

Afghanistan, Algeria, Angola, Armenia, Azerbaijan, Bangladesh, Belize, Benin, Bhutan, Bolivia (Plurinational State of), Botswana, Burkina Faso, Burundi, Cabo Verde, Cambodia, Cameroon, Central African Republic, Chad, Comoros, Congo, democratic Republic of the, Congo, Costa Rica, Côte d'Ivoire, Cuba, Djibouti, Dominica, Dominican Republic, Ecuador, Egypt, El Salvador, Equatorial Guinea, Eritrea, Eswatini, Ethiopia, Fiji, Gabon, Gambia (the), Georgia, Ghana, Grenada, Guatemala, Guyana, Guinea, Guinea-Bissau, Haiti, Honduras, India, Iran (Islamic Republic of), Iraq, Jamaica, Jordan, Kazakhstan, Kenya, Kiribati, Korea (Democratic People's Republic of), Kosovo, Kyrgyzstan, Lao People's Democratic Republic (the), Lesotho, Liberia, Libya, Madagascar, Malawi, Maldives, Mali, Marshall Islands, Mauritania, Mauritius, Micronesia (Federated States of), Moldova, Republic of, Mongolia, Morocco, Mozambique, Myanmar, Namibia, Nepal, Nicaragua, Niger, Nigeria, Pakistan, Papua New Guinea, Paraguay, Peru, Philippines, Rwanda, Saint Lucia, Saint Vincent and the Grenadines, Samoa, Sao Tome and Principe, Senegal, Seychelles, Sierra Leone, Solomon Islands, Somalia, South Africa, South Sudan, Sri Lanka, Sudan, Suriname, Syrian Arab Republic, Tajikistan, Tanzania, United Republic of, Timor-Leste, Togo, Tonga, Tunisia, Tuvalu, Uganda, Ukraine, Uzbekistan, Vanuatu, Venezuela (Bolivarian Republic of), Viet Nam, West Bank and Gaza, Yemen, Zambia, Zimbabwe

# Table 3 Licensees that have taken tech know-how package and thus cannot produce finished pharmaceutical product for domestic use or export to an importing country outside the listed territory

Covid Antiviral	Licensee Companies
Molnupirvair	Fosun (WHO PQ pending)
Nirmatrelvir	CPT, Hikma, Kimia, Remington (WHO PQ intentions unknown) Hetero Labs Limited (WHO PQ)*
Nimateivi	Celltrion, Fosun, and Mylan (WHO PQ)
	Amneal, Apeloa, Aurobindo, Biocon, Cadila Pharmaceuticals Ltd., Cipla, Darnitsa, Divi's, DongBang, Emcure, FHI Zdaravlje, Glenmark Lifesciences, Glenmark Pharma, Granules, Hikma Pharmaceuticals, Jiuzhou, Laurus, Macleods, Magnachem, MSN, Neolpharma, Remington, SMS Pharma, Sun Pharmaceutical Industries Ltd., Torrent
	*Hetero is the sole WHO PQ licensee, but took the tech know-how package is therefore not authorized to sell or export outside the licensed territory ** These three companies will also not be able to supply outside the licensed territory.

#### **Regulatory Status**

In addition to addressing intellectual property barriers, countries will be concerned about regulatory status, both in terms of whether the manufacturer has passed WHO Prequalification or Emergency Use Listing and whether the manufacturer's covid antiviral is authorized for use by a country's national regulatory authority. (Note: it is beyond the scope of this analysis to identify which countries have granted regulatory approval, but numerical information from MPP as of 6/30/2023 is provided.) **Table 4** lists the MPP licensees that have applied for or received WHO prequalification and thus can produce and sell under the relevant license. Unfortunately, only a handful of companies have been prequalified by the WHO, though several others are pending approval. **Table 4** also gives a numerical overview of the number of countries that have granted national regulatory approval for marketing and use of covid antivirals or that have submitted dossiers awaiting approval. WHO PQ has apparently stopped reporting on the pending status of named PQ applicants, which is unfortunate. The company-specific Information provided in **Table 4** came from such reporting on an earlier webpage that is no longer available.

Note: An additional advantage of sourcing from an MPP licensee that is prequalified is that some licensees have committed to affordable pricing as low as \$25 per course of treatment for nirmatrelvir, depending on quantities ordered.

Covid Antiviral	WHO Prequalified	Under WHO PQ	Nat'l Regulatory
		Review	Status
Molnupiravir	FPP: Hetero, Dr.	Fosun (will not be	MOL (200 mg)
	Reddy, Emcure (all	able to supply outside	Filed in
	can supply outside	territory if PQ'ed	15 countries
	the territory if no	because it took tech	Approved
	patent is pending or	package)	in <b>5</b> countries:
	granted or a CL is		Guatemala, India,
	issued since they did	Aurobindo, Cipla,	Indonesia,
	not take a tech	Mylan, Shanghai	Philippines, Viet
	package)	Desano, and Strides	Nam
		(will be able to supply	Supplied
	API: Emcure, Divi's,	outside licensed	in <b>2</b> countries:
	Aurobindo	territory)	Guatemala, India
Nirmatrelvir	FPP: Pfizer,	Celltrion, Fosun,	NIR (300 mg)
	Hetero (cannot supply	Mylan will not be able	Filed in
	outside the territory	to supply outside	19 countries
	because it took tech	territory because of	Approved
	package)	tech package.	in 4 countries:
		Zhejiang Apeloa	Cambodia,
	API: Zhejiang Jiuzhou,	Kangyu, Zhefiang	Ethiopia, India,
	Shanghi Desano	Huahai Pharm would	Malawi
		be able supply	Supplied
			in 5 countries:
			Cambodia,
			Cameroon,
			Eswatini, Ghana,
			Zambia
Ensitrelvir Fumaric Acid	Shionogi not yet PQed		EUA in Japan

## Table 4 WHO Prequalification Status of COVID-19 Medicines 26 June 2023,Nat'l Regulatory Status and Supply as of 6/30/2023

#### Conclusions:

Many middle-income countries are seriously disadvantaged in securing access to generic covid antivirals. Twenty countries/territories are currently excluded from the licensed territories of all three MPP licenses and another 28 are excluded from at least one license. Examination of patent status reveals that most of these excluded countries face a pending or granted patent bar to generic access to one or more antivirals in the absence of a domestic compulsory license (and another CL may be required in the country of manufacture/export). A few excluded countries (patent status marked in green) do not face a domestic patent barrier but access may depend on a CL being issued in the country of exportation. Unfortunately, Hetero, the sole licensed and prequalified generic producer, cannot supply nirmatrelvir outside the Pfizer licensed territory, whereas three molnupiravir licensees can supply to unlicensed territories but only if other nopatent, compulsory-licensing, and regulatory requirements are met.

A glaring weakness in the architecture of MPP licenses is apparent in this review. Patent holders, particularly those owning patents to more complex medicines, offer technology transfer packages as part of their licenses, but the offer comes with significant strings attached that end up making territorial restrictions ironclad. Although MPP licenses routinely have exceptions to allow supply licensees to supply countries where there are no blocking patents or where compulsory licenses have been issued (and do so to avoid undermining TRIPS flexibilities), trade-secret-based technology transfer packets act as exception to the exception and take away the CL-based supply right that licensees would otherwise have to supply outside the licensed territory. Licensees are eager to take the tech package, as they've done with nirmaltrevir and molnupiravir, because of their desire to expedite production and/or to gain technical knowledge without which quality-assured commercial-scale manufacturing might be difficult, expensive, time-consuming, or even impossible to acquire or develop on their own.

It is questionable, but now apparently routine, to allow access to trade secrets to operate as an independent basis for restricting extra-territorial access even to countries where there is no blocking patent in existence or where a proper compulsory license has been issued. Although not expressly stated in the licenses, trade-secret-based territorial limitations might last longer than patent-based ones, which expire twenty years after the last blocking patent. Trade-secret limitations might last as long as the information remains "confidential" and of commercial value.

The net result of the trade-secret-related territorial restriction is that excluded countries, mostly upper-middle-income, will need to source from companies that are not MPP licensees, at least where existing MPP licensees have all taken tech transfer packages. If certain MPP licensees have not taken the technology transfer package then theoretically at least they are contractually authorized to supply where there are no blocking patents or a compulsory license has been issued in the supplied country.