Gilead's Hepatitis C Medicines License – Troubling Territorial Exclusions, Illusory Exceptions, and Tiered Pricing Policy Fracture Global Access

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Introduction to basic licensing terms

Gilead has just announced and released the text of its license on two direct-acting oral antivirals (DAAs) used to treat hepatitis C virus (HCV) infections, sofosbuvir (Sovaldi®) and ledipasvir. The License allows seven Indian generic companies – Cadila Healthcare Ltd., Cipla Ltd., Hetero Labs Ltd., Mylan Laboratories Ltd., Ranbaxy Laboratories Ltd., Sequent Scientific Ltd. and Strides Arcolab Ltd. – to manufacture, distribute and sell the individual products and a combination pill of the two products in a subset of 91 low- and middle-income countries (see list attached).

The basic terms and conditions of the license are relatively straightforward. The active pharmaceutical ingredients (APIs) must be manufactured and sourced from licensed API suppliers in India (¶ 2.1(a), ¶ 3). The license will allow co-formulation of sofosbuvir and ledipasvir with other companies' HCV medicines (¶ 2.3(c)),[1] and in the future Gilead's pan-genotypic pipeline DAAs, including GS 5816, will be added to the license (¶ 2.5). Generic licensees will pay a 7% net royalty on the licensed products regardless of patent status in the country of use, based, at this time, on challenged patent applications in India (¶ 4.1).[2] Licensees are required to report improvements (¶ 5.3) and grant a royalty free license on all product improvement back to Gilead (¶ 2.2). Gilead is offering a one-time technology transfer (¶ 5.5)[3] and non-proprietary data and regulatory waivers with respect to the registration process (¶ 6.3). Gilead will supervise quality standards (¶ 6.2) and insist on registration before generic sales are consummated (¶ 6.3). It also will require stringent anti-diversion (¶ 6.1(a), ¶ 7.2) and product differentiation measures (¶ 5.4(a)) that allow it to unilaterally terminate a license if it believes that material quantities of a licensee's generic are being diverted to non-licensed territories (¶ 10.3(b)). Generic licensees may not terminate the license with respect to any covered product until five years have passed (¶ 10.4).[4]

The licensed territory covers approximately 100 million people but it leaves 49 million people in middle-income countries without generic access

Gilead estimates that the licensed territory covers over 100 million people, approximately 54% of people living with HCV in the world – meaning that 46% of people infected are left outside the licensed territory. Gilead is non-defensive about its exclusion of upper-income country

[1] Note: There is some inconsistency between this stated right and the description of "dose requirements" in ¶ 6.2(d) of the License, which limits product sold to single dose or combination Sof and LDV and also requiring that the product have been approved by the U.S. Food and Drug Administration or by DCGI and the appropriate medicines regulatory question in the country of sale.

[2] Regrettably, Gilead proposes to still collect royalties even if patents in India and in a covered territory are not granted (¶ 4.1(h)), though Gilead does commit to negotiating a reduced royalty. Gilead may think it is entitled to some royalty even where there are no patents because of its technology transfer provision.

[3] The technology transfer are unbundled meaning that licensees can take all, some, or none.

[4] In discussions about the license, Gilead said that licensees not taking the technology transfer could terminate sooner than five years, but that option is not clearly described in the license itself.

markets (15% of the global market with approximately 27.75 million infected) including North America, Western Europe, and Japan where it expects multi-billion dollar annual sales and profits based on a per patient treatment cost for sofosbuvir alone as high as $84,000 for a 12-week course of treatment. (The combo product will reportedly be sold at more than $95,000 per patient in the US when approved.[5])

Although the License grants 100% coverage for low-income countries, it excludes 51 middle-income countries, including 13 lower-middle income countries and 38 upper-middle income countries (see list attached). The excluded number of people living with HCV in middle-income countries is over 49 million based on 2010 global epidemiological estimates. This represents approximately 43% of the middle-income country total. The country with the largest excluded population is China with nearly 30 million people infected. Brazil (2,609,607), the Philippine (1,932,854), Ukraine (1864,840), Turkey (1,549,108), Thailand (1,499,058) Mexico (1,106,450), and Romania (1,003,680) are other middle-income countries with over one million excluded. As discussed further below, the territorial limitation will be quite problematic for people infected in excluded middle-income countries, especially given the license's definitions of patent rights protected and the narrow and perhaps illusory window for bypassing the License's prohibition of extra-territorial sales.

The License should also be understood and evaluated in light of Gilead's planned tiered-pricing policies whereby it will attempt to maintain its monopoly control over this 50-million person market. As a patent holder – or even as a patent applicant, Gilead can exclude competitors and charge profit-maximizing prices on its life-saving HCV medicines. Its current plan seems to be to offer an access price of $900 for 12 weeks of treatment or $1800 for 24 weeks of treatment in its 60-country low-income country category, which includes India and Brazil[6] – a price that generic entrants will have to compete against – with significantly higher prices in lower-middle income countries and even higher prices in upper-middle income markets. In discussion with advocates, Gilead has said that it would set prices in the newly added lower-middle income and upper-middle income tiers according to predetermined bands and that it would negotiate country-by-country; those price bands have not been publicly disclosed. Gilead averred that it would lower prices in the future if governments commit to expansive treatment programs and if they adopted liberal treatment guidelines. In sum, Gilead still sits in the driver's seat and has enormous power to decide who does and doesn't get its most favorable price. In all instances, Gilead's tiered prices in lower- and upper-middle income countries will be hundreds or even thousands of dollars more expensive per treatment than with generics.

Gilead's definition of product patents and its insistence on preventing extra-territorial sales if there is "any reasonable possibility of obtaining a product patent within a reasonable period of time" means that it will be very difficult – nearly impossible – for licensees to supply from India or elsewhere to excluded countries.

Pursuant to Paragraph 10(C), Gilead has created a narrow, essentially illusory window for allowing licenses to sell outside the licensed territory.

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[5] Deena Beasley, *Gilead to raise price for new hepatitis C drug above $84,000*, Reuters (Sept. 12, 2014) http://206.132.6.101/article/2014/09/12/us-gilead-sovaldi-idUSKBN0H72KR20140912.

[6] In creating this category, which is not just GNI/capita based, Gilead apparently takes into account prevalence rates as well. It is believed that the 60 countries originally discussed might be the "low-income" countries entitled to this lowest "discount" price.

(i) For clarity, and notwithstanding anything to the contrary in this Agreement, with respect to a particular Product, and on a Product-by-Product and country-by-country basis, if there is no Product Patent owned or controlled by Gilead (or its Affiliates) in India and a particular country outside of the Territory, and if there is **no reasonable possibility of obtaining such a Product Patent within a reasonable period of time (for example, through pending patent applications, the filing of patent applications, or by legal action (including appeals)) in India and such country outside of the Territory**, it shall not be deemed to be a breach of this Agreement for Licensee to supply such Product in such country and Licensee shall not be obligated to pay Gilead any royalty therefor; provided that Licensee obtained applicable regulatory approval in such country (emphasis added).
(ii) Similarly, on an API-by-API and Product-by-Product basis, it shall not be deemed to be a breach of the Agreement for Licensee: (x) to manufacture API in any country where there is no Product Patent owned or controlled by Gilead (or its Affiliates) covering such API in such country, and there is **no reasonable possibility of obtaining such a Product Patent within a reasonable period of time (for example, through pending patent applications, the filing of patent applications, or by legal action (including appeals) in such country**; (y) to sell such API referred to in clause (x) of this Section 10.3(c)(ii) in any country where there is no Product Patent owned or controlled by Gilead (or its Affiliates) covering such API in such country, and there is **no reasonable possibility of obtaining such a Product Patent within a reasonable period of time (for example, through pending patent applications, the filing of patent applications, or by legal action (including appeals) in such country**; or (z) to manufacture and/or sell Product incorporating such API referred to in clause (x) of this Section 10.3(c)(ii) in in any country where there is no Product Patent owned or controlled by Gilead (or its Affiliates) covering such Product (or the API contained therein) in such country, and there is **no reasonable possibility of obtaining such a Product Patent within a reasonable period of time (for example, through pending patent applications, the filing of patent applications, or by legal action (including appeals) in such country**.

Gilead holds a lot of cards with its definition of "reasonable possibility of obtaining a product patent." This at the very least covers patents already filed but not granted (¶ 4.1(h)); patents in the pipeline, e.g., Patent Cooperation Treaty applications, of there are several listed in the License's appendix; patents where new divisional or selection or amended applications patents are possible;[7] and patents that can still be filed within the Paris Treaty one-year grace period window.[8] With this definition, Gilead is clearly taking advantages of loopholes in the patent system that give pending patent applications almost as much deterrent value as a granted patent. Plus, analysts know that companies, including Gilead, are willing to game the patent system with recursive patent applications, divisional/selection patents, patent amendments, etc. and with endless appeals if their patent is not granted. Using the Novartis' Glivec case as an example, it took over seven years to achieve the level of finality that would satisfy the Gilead license provision (patent denied January 2006, Supreme Court judgment April 2013).

With the existing language concerning the "reasonable possibility of a patent being granted", supply outside the territory can occur easily only if the generic licensee manufactures "outside the license" in a country other than India and no patent is pending or reasonably expected in that country. In addition, the country to which the generic product is to be exported and used must also be without any pending or reasonably anticipated product patent. In the more

[7] These applications can really proliferate and now appear to be a key part of companies' evergreening strategy. After an original patent application is opposed, the applicant stays in the driver's seat by amending, dividing, or selecting patent claims requiring a whole new cycle of patent examinations, oppositions, and eventual appeals.
[8] *See* Paris Convention for the Protection of Industrial Property, Art. 4.C(1).

common case, however, there will be a patent pending in India or any other country of production, i.e., China, and a product patent pending or reasonably expected in the country of importation and use. In these circumstances, the generic licensee will have to twiddle its fingers for years waiting for Gilead's evergreening strategies to play their way out (or it will have to seek compulsory licenses as discussed further below.) These licensees do not really have the option of testing the waters – "infringing" then defending – because to do so does not expose them simply to infringement claims but will immediately subject them to license termination.

Although it is true that some unlicensed generic companies could decide to take the risk and manufacture in a patent-free India – assuming all Indian oppositions are successful and that appeals are denied – or in a country other than India where no patent was pending in order to supply to an excluded territory, this seems unlikely. Supplying such countries would create liability risks where national legislation allows retroactive damages for infringements occurring during patent pendency. For this reason, patent pendency is enough to deter most generics unless the patent is fatally flawed on its face. Another practical problem that generic companies might face in supplying extra-territorial markets is that it might not be easy to discover Gilead's patent and pending patent landscape in excluded countries, especially since Gilead persists in refusing to disclose such information.

Gilead's compulsory licensing exception allowing extra-territorial sales might also prove difficult to use in practice

Paragraph 10(d) of Gilead's license allows generic licensees to become compulsory licensees to manufacture and sell if there is: (1) a compulsory license issued in the country of import, (required only if there are any relevant product patents or patent applications) and/or (2) an export license in India (only required if any relevant product patents or patent applications are pending).

> (d) For further clarity, and notwithstanding anything to the contrary in this Agreement, it shall not be deemed to be a breach of the Agreement for Licensee to supply an API or Product outside the Territory into a country where:
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> > (i) the government of such country has issued a Compulsory License relating to such API or Product allowing for the importation of such API or Product into such country, provided that Licensee's supply of Product or API into such country is solely within the scope and geographic range of such Compulsory License and only for the duration that such Compulsory License is in effect; and/or (ii) the Government of India has issued a Compulsory License allowing for the export of an API or Product from India and into such country, provided that: (Y)(1) there are no Product Patents owned or controlled by Gilead (or its Affiliates) issued in such country or (2) a Compulsory License has also been issued by the relevant authorities of such country; and (Z) Licensee's supply of Product or API into such country is solely within the scope and geographic range of the Compulsory License issued by the Government of India, and only for the duration that such Compulsory License is in effect.

In the normal case, in order to supply an excluded territory, the generic licensee would have to be granted a compulsory license in the country of production (India) or in the country of importation or both – in essence wherever a patent or pending patent exists.

A special problem could arise if there is uncertainty whether it is permissible to grant a compulsory license on a pending patent as opposed to a granted patent. If such an interpretation occurred, this could mean that generics might have to wait until a patent is

granted before prosecuting a compulsory license application. Fortunately, the superior interpretation of compulsory licensing rules should allow involuntary use on all active and pending patents covering the licensed medicine. It would defeat the purpose of compulsory licensing and government use rules if pending patent applications bound the state and competitors more tightly than granted patents with respect to involuntary use.

Nonetheless, an additional problem with respect to compulsory licensing is that it might require detailed knowledge of patent filings and status of patent applications in excluded countries – a task that would be much easier if Gilead were to disclose its global patent landscape on sofosbuvir and ledipasvir, which it currently refuses to do. This problem could presumably be overcome by the compulsory license application seeking coverage of all pending and granted patents covering the medicines in question.

Gilead's intentions for excluded countries – is tiered pricing and intra-country sector segmentation and price differentiation good enough?

The essence of Gilead's current license is to grant early access in 91 select countries in exchange for receipt of royalty payments collected even where patents have not been filed or granted, mainly on the basis of pending and challenged patent applications in India. In addition, Gilead has announced tiered pricing plans whereby the company offers lower prices in different income countries for its branded HCV medicines, and differential pricing between the public/voluntary sector and the private sector even in those countries. Using common drug company metrics, Gilead plans to offer different price bands for the public sector and select NGOs in low-income, lower-middle-income countries and upper-middle-income countries. With the exception of low-income countries where Gilead is on record saying that it will have a uniform access price of $900 for a 12-week course of treatment with sofosbuvir, it appears unlikely that the public/NGO sector tiered pricing will be uniform within each tier; instead, Gilead plans to negotiate country-by-county, particularly in the upper-middle-income country tier. Early conservative estimates show that Gilead's tiered pricing strategy could increase the price of production of curing hepatitis C by a conservative estimate of $60 billion.[9]

Gilead had previously announced imminent deals with Egypt and India that promise a probable price of $900 for a standard 12-week course of treatment with sofosbuvir. However, this price is reportedly only applicable for the public sector and non-governmental organizations engaged in demonstration projects. Meanwhile, Gilead has indicated that it will charge substantially higher prices in the private sector. As a consequence, since only a handful of middle-income countries are able to introduce comprehensive public sector treatment programs, especially in the absence of donor funding, most patients will have to access sofosbuvir out-of-pocket and solely through the private sector at much higher prices. The total price paid for treatment would even be higher because sofosbuvir must be combined with other medicines to achieve maximum effect.

By means of its tiered pricing, sector-segmentation strategy, Gilead is trying to maximize its profits in middle-income countries excluded from the license by fully controlling sales to both public, NGO, and private sectors. In this way, Gilead aims to fragment the generic and brand-name tiered-pricing markets, leaving its generic licensees unable to achieve maximum

[9] I-Mak, *Press Backgrounder for Sofosbuvir* (Sept. 15, 2014), available at http://tinyurl.com/lnuqrut.

economies of scale by excluding them from some of their most lucrative potential markets. Meanwhile, Gilead will make significant profits on large-volume sales in excluded territories given the huge differential between the projected cost of producing a 12 week supply of sofosbuvir (estimated at $100, range $68-136[10]) and projected prices for public/NGO sector sales and even higher price for private sector sales. Spread over millions of LMIC sales per year, Gilead's LMIC profits will eventually add nicely to the excess profits it already reaps in rich country markets where it earned $5.8 billion in the first six months based on its upper-income country price in the US and Western Europe of $600 to $1000 a pill.

For excluded middle-income that don't like living under Gilead's tiered-pricing, sector-segmentation tyranny, the license effectively limits their policy options. Perhaps the most anti-competitive aspect of Gilead's plan is that it will lock leading generic producers into licenses that will make it very difficult for there to be generic producers for Gilead's DAAs in the excluded middle-income countries. None of the licenses will be willing to risk license termination to test the edges of Gilead's "no reasonable possibility of a product patent" and "all necessary compulsory licenses" requirements. Even if a qualified generic that is not a licensee decided to test Gilead's patents or to seek compulsory licenses, it would face a relatively small and fractured market and one where robust competition is far less likely

How significantly will Gilead's license lower prices – not quickly and not as much as it could

Gilead's license will probably lead to phased availability of generic equivalents and of country use over a protracted period of time. At the very least, many months will be required to develop the product for commercial production, to prosecute product registration, and to establish distribution schemes. In the meantime, Gilead is not offering radical price discounts other than in low-income markets.

Gilead is on record saying that its licensees can set prices at their own discretion. As stated above, the cost of production for a 3-month course of sofosbuvir is relatively modest, estimated between $68-$136, and the stated royalties will be 7%. Production costs will get to the lower end of the estimated cost range, the more efficiently and competitively active pharmaceutical ingredients (API) and final formulations are produced. Unfortunately, the anticipated Gilead license might not result in the lowest possible prices because the size of the generic market is limited to only a portion of people living with HCV, mostly those in poorer and higher prevalence countries. Generic manufacturers will not necessarily be producing at the most efficient economies-of-scale and there will be fewer successful generic competitors[11] because the smaller and generally poorer markets will be less attractive to generic producers. Generic entrants might be particularly reluctant to serve all smaller volume, poorer countries because of the costs of registering their products and establishing distribution systems.

Moreover, regardless of the significant number of licensees, price reductions will not necessarily occur immediately and volumes might initially be small. As discussed above, licensees have to register their medicines in licensed territories and arrange marketing and distribution systems

[10] Andrew Hill et al., *Minimum costs for producing Hepatitis C Direct Acting Antivirals, for use in large-scale treatment access programs in developing countries*, 58:7 Clin. Infect. Dis. 928-936 (2014), available at http://cid.oxfordjournals.org/content/58/7/928.full.pdf+html.

[11] Gilead is purportedly negotiating with at least the following companies: Hetero Drugs Ltd., Mylan Inc., Cipla, Ranbaxy, Strides Acrolab.

and both of these can take a lot of time. In addition, there are no donors at present that are helping countries or patients by subsidizing the costs of HCV treatment. Accordingly, actual treatment access might initially be quite low, especially in licensed poorer and high prevalence countries where health sector budgets are limited.

Gilead's license is a partial step forward, but ultimately it will delay universal access and the erdication of HCV

Perhaps the most important critique of Gilead's license – and its related tiered-pricing, market-segmentation policy – is that they do not ensure universal, affordable access to it lifesaving drugs. Hepatitis C virus is an infectious disease just like HIV. Globally an estimated 185 million people have been infected[12] and there are 3-4 million new infections and 350,000+ deaths annually. Unlike HIV, HCV can now be cured. When a person is cured of Hep C, he or she is no longer infectious, meaning the more people cured with affordable treatments, the quicker the pandemic will end.

Countries (and donors) are more likely to invest in universal access to an HCV cure if the medicines are available at their most affordable cost. With a low-enough price, even patients who are not actively progressing with HCV-related liver disease will be treated to eliminate the virus and the risk of onward transmission. (This is the strategy used in rich countries to cure latent tuberculosis and is increasingly the strategy for tackling HIV and AIDS.)

Unfortunately, Gilead's License is not well designed at present to end the HCV pandemic. The License fails to cover 43% of people living with HCV in middle-income markets. Gilead's market fragmentation approach will lead to higher than necessary prices even in licensed territories and ultimately to less than universal access. That means that this License misses both the target of worldwide equitable access to treatment and the ultimate goal of accelerating HCV eradication. Many additional efforts will be needed to achieve eradication, including improved diagnostics and linkages to care and improved therapies.[13] Also important will be efforts to address the needs of most affected populations, most especially people who inject drugs who require massive scale-up of harm reduction programming, removal of structural barriers to treatment,

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[12] Hanafiah K Mohd et al., *Global epidemiology of hepatitis C virus infection: new estimates of age-specific antibody to HCV seroprevalence* 57:4 Hepatology 1333-42 (2013).

[13] Wei, L. and Lok, ASF. Impact of New Hepatitis C Treatments in Different Regions of the World. Gastroenterology. Published Online: March 21, 2014 DOI: http://dx.doi.org/10.1053/j.gastro.2014.03.008. Available at: http://www.gastrojournal.org/article/S0016-5085(14)00357-6/fulltext.

Barriers That Need to Be Overcome to Achieve HCV Eradication
- Detect persons who are infected
  - Identification of high-risk/high-prevalence groups
  - Availability of sensitive, specific, and affordable tests for screening and for confirmation of infection
  - Screening programs that are practical and tailored to individual countries or settings
  - Public awareness of risk groups, sequelae, and treatment options
- Link infected persons to care
  - Access to care for all infected persons
  - Availability of trained health care providers and resources to manage infected persons
- Eradicate HCV with safe and effective drugs
  - Development of drugs that are potent, safe, and have pangenotype activity
  - Development of treatment regimens that are simple and effective against all HCV genotypes and all stages of liver disease
  - Availability of safe and efficacious drugs at affordable price

and measures that address stigma and discrimination and advance a human rights based approach. None of these other efforts will come to fruition, however, unless Gilead and other DAA producers make their therapies universally available and affordable.

Gilead is by no means the only company that is failing to contribute as much as it might to HCV treatment globally. All the other DAA innovators – Merck, Bristol-Myers Squibb, AbbVie and Johnson and Johnson are sitting on the sidelines. People living with hepatitis C need those companies' medicine too, especially DAAs that are pan-genotypic. Pan-genotypic medicines will reduce the need for complex diagnostics and thereby simplify treatment. All companies in with DAA for treating HCV should broadly license their medicines and allow them to be co-formulated into the most efficacious and most affordable treatments. With this license, Gilead has taken two steps forward but it refuses to take the third. That third leaves 50 million people risk in excluded territories and the failure to take the final step also weakens the license's impact in included territories.

Included Territory

1. Afghanistan
2. Angola
3. Antigua and Barbuda
4. Bangladesh
5. Benin
6. Bhutan
7. Bolivia
8. Botswana
9. Burkina Faso
10. Burundi
11. Cambodia
12. Cameroon
13. Cape Verde
14. Central African Republic
15. Chad
16. Comoros
17. Congo, Rep
18. Congo, Dem. Rep. of the
19. Côte d'Ivoire
20. Cuba
21. Djibouti
22. Dominica
23. Egypt
24. Eritrea
25. Ethiopia
26. Equatorial Guinea
27. Fiji
28. Gabon
29. Gambia
30. Ghana
31. Guatemala
32. Guinea
33. Guinea-Bissau
34. Guyana
35. Haiti
36. Honduras
37. India
38. Indonesia
39. Kenya
40. Kiribati
41. Kyrgyzstan
42. Lao, People's Dem. Rep.
43. Lesotho
44. Liberia
45. Madagascar
46. Malawi
47. Maldives
48. Mali
49. Mauritania
50. Mauritius
51. Mongolia
52. Mozambique
53. Myanmar
54. Namibia
55. Nauru
56. Nepal
57. Nicaragua
58. Niger
59. Nigeria
60. North Korea
61. Pakistan
62. Palau
63. Papua NewGuinea
64. Rwanda
65. Samoa
66. São Tomé and Príncipe
67. Senegal
68. Seychelles
69. Sierra Leone
70. Solomon Islands
71. Somalia
72. South Africa
73. South Sudan
74. Sri Lanka
75. St. Vincent and the Grenadines
76. Sudan
77. Surinam
78. Swaziland
79. Tajikistan
80. Tanzania, U. Rep. of
81. Timor-Leste
82. Togo
83. Tonga
84. Turkmenistan
85. Tuvalu
86. Uganda
87. Uzbekistan
88. Vanuatu
89. Vietnam
90. Zambia
91. Zimbabwe

Excluded Territory and HCV Infected

Lower-Middle Income (13)	# of HCV Infected
1. Armenia	133012
2. El Salvador	164689
3. Georgia	328945
4. Kosovo	
5. Micronesia	2200
6. Moldova	99498
7. Morocco	624,953
8. Paraguay	76162
9. Philippines	1932854
10. Syria	94405
11. Ukraine	1864840
12. West Bank & Gaza	
13. Yemen, R.	412352
Upper-Middle Income (38)	
1. Albania	53172
2. Algeria	70846
3. America Samoa	
4. Argentina	743750
5. Azerbaijan	314735
6. Belarus	226600
7. Belize	2100
8. Bosnia Herzegovina	58605
9. Brazil	2609670
10. Bulgaria	139068
11. China	29791212
12. Columbia	425191
13. Costa Rica	32453
14. Dominican Republic	66713
15. Ecuador	195605
16. Grenada	5150
17. Hungary	219582
18. Iran	630450
19. Iraq	834600
20. Jamaica	20250
21. Jordan	114660
22. Kazakhstan	474592
23. Lebanon	31850
24. Libya	104736
25. Macedonia	40800
26. Malaysia	397515
27. Marshall Islands	900
28. Mexico	1106450
29. Montenegro	10980
30. Panama	22500
31. Peru	284100
32. Romania	1003680
33. Serbia	156345
34. St. Lucia	1232
35. Thailand	1499058
36. Tunisia	124488
37. Turkey	1549108
38. Venezuela	272976
51 Countries	**49,369,632**