



**2014**

**A Review of the Bedaquiline  
Patent Landscape  
A scoping report**

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### 1. INTRODUCTION

The World Health Organization (WHO) estimates that a third of the world's population is latently infected with *Mycobacterium tuberculosis*. In 2012, there were an estimated 8.6 million incident cases of tuberculosis (TB), with 12 million prevalent cases, 940 000 deaths among HIV-negative people, and 320 000 deaths among HIV-positive people.<sup>1</sup> Most cases (58%) were in the WHO South-East Asia and Western Pacific regions, while the WHO African region had 27% of the world's cases. Despite being curable, TB claimed the lives of 1.3 million people in 2012.

TB treatment has become more complex, particularly with the emergence of multidrug-resistant (MDR) strains of *Mycobacterium tuberculosis*. There were approximately 450 000 new cases of multidrug-resistant tuberculosis (MDR-TB) worldwide in 2012.<sup>1</sup> MDR-TB is resistant to the two most commonly used TB drugs, isoniazid and rifampicin. It requires extended treatment with second-line drugs that are less effective and have more adverse effects than isoniazid- and rifampicin-based regimens.<sup>2</sup>

Given the emergence of MDR-TB, and the need to shorten treatment duration, new drugs are required. The last of the current anti-TB treatments – rifampicin – was introduced in 1963. Since then, research for new TB treatments had largely come to a halt. However, in recent years the pipeline for potential new TB treatments has started to look more promising than it has for the past 50 years.

One compound of interest is Johnson & Johnson's (J&J)/Janssen's recently approved diarylquinoline compound bedaquiline, which is marketed under the brand name Sirturo. Bedaquiline is a new treatment, approved for MDR-TB, and under development for drug susceptible tuberculosis (DS-TB). Given that bedaquiline is the first new treatment for TB, this report explores the patent landscape and considers possible access issues relating to this drug.

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1 Global tuberculosis report 2013. Geneva: World Health Organization; 2013 ([http://www.who.int/tb/publications/global\\_report/en/](http://www.who.int/tb/publications/global_report/en/), accessed 31 December 2013).

2 Diacon.A et al. The diarylquinoline TMC207 for multidrug-resistant tuberculosis. *New England Journal of Medicine*. 2009;360:2397–2405.

## 2. BACKGROUND

Janssen Pharmaceutica (a subsidiary of J&J) discovered bedaquiline (initially referred to as TMC207) around 2002 while screening for compounds that would kill *Mycobacterium smegmatis*, a saprophytic distant relative of *Mycobacterium tuberculosis*. Bedaquiline falls into the class of compounds known as diarylquinolines (DARQs), also referred to as substituted quinoline derivatives.

Chemical names for bedaquiline:

- 3-quinolineethanol, 6-bromo- $\alpha$ -[2-(dimethylamino)ethyl]-2-methoxy- $\alpha$ -1-naphthalenyl-  $\beta$ -phenyl-, ( $\alpha$ S, $\beta$ R)-; and
- (1R,2S)-1-(6-bromo-2-methoxyquinolin-3-yl)-4-(dimethylamino)-2-(naphthalen-1-yl)-1-phenylbutan-2-ol.

The structure of bedaquiline is shown in Figure 1.

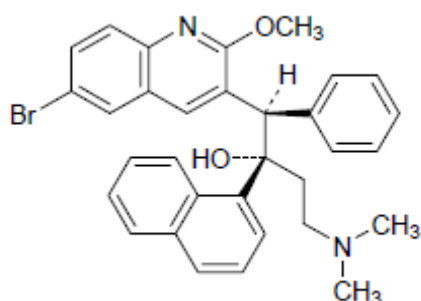


Figure 1. Structure of bedaquiline

Structurally and mechanistically, DARQs are different from both fluoroquinolones (including methoxyquinolones) and other quinoline classes.<sup>3</sup> In vitro studies have shown that bedaquiline offers a new mechanism of anti-tuberculosis action by specifically inhibiting mycobacterial adenosine triphosphate (ATP) synthase. More significantly, bedaquiline has been shown to potentially inhibit DS-TB, MDR-TB and latent TB.

In June 2009, the Global Alliance for TB Drug Development (TB Alliance), a not-for-profit product development partnership (PDP), and Tibotec Inc. (also a J&J subsidiary and affiliate of Janssen) announced they were to collaborate in sharing their expertise and resources in the development of bedaquiline.<sup>4</sup> According to its press statement, and as confirmed by the TB Alliance, under the terms of the agreement Tibotec would develop bedaquiline for the treatment of MDR-TB and, on approval, establish an access programme.<sup>5</sup> Therefore, Tibotec<sup>6</sup> would be solely responsible for the marketing and access programme of bedaquiline for MDR-TB.

The TB Alliance has a royalty-free licence for the worldwide development of, and access to, bedaquiline in the field of DS-TB. Janssen/Tibotec/J&J will, however, maintain intellectual property rights to bedaquiline (see below for more detailed discussion).

In December 2012, the United States Food and Drug Administration (FDA) granted bedaquiline accelerated approval for the treatment of MDR-TB in adults.<sup>7</sup> This approval is only for marketing in the USA. Janssen

3 Andries K et al. A diarylquinoline drug active on the ATP synthase of *Mycobacterium tuberculosis*. *Science*. 2005;307:223–227. Substituted quinolines for treating antibiotic-resistant bacterial microorganisms and inhibiting their growth have been disclosed in earlier patents. See US Patent No. 5965,572 and WO 2000/034265.

4 Tibotec. Unique collaboration between TB Alliance and Tibotec to accelerate tuberculosis drug development. 17 June 2009 (see <http://www.prnewswire.com/news-releases/unique-collaboration-between-tb-alliance-and-tibotec-to-accelerate-tuberculosis-drug-development-62146782.html>, accessed 31 December 2013).

5 Meeting with the TB Alliance at the 42<sup>nd</sup> Union World Conference on Lung Health, 29 October 2011, Lille, France.

6 Now Janssen Therapeutics, a part of Janssen Pharmaceutical Companies.

7 FDA news release (<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm333695.htm>, accessed 31 December 2013).

## A Review of the Bedaquiline Patent Landscape

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will have to register the product with the national authorities of other countries where it intends to sell the product. Janssen has submitted applications for regulatory approval in China, the European Union, India, South Africa, Thailand and Viet Nam.<sup>8,9</sup>

The recommended dose is 400 mg once daily for two weeks, followed by 200 mg three times per week for 22 weeks.<sup>10</sup> As the FDA granted accelerated approval for bedaquiline, Janssen will have to conduct further post-marketing studies to verify the drug's benefit. The FDA's specific requirements include:

- A Phase III trial should be conducted and a report prepared assessing long-term outcomes of treatment failure, relapse or death at least six months after all treatment is completed.
- The incidence of serious adverse events should be assessed in all patients given bedaquiline in the USA.
- A drug interaction trial of bedaquiline and efavirenz should be conducted to determine a safe and effective dose regimen for both drugs when co-administered in people co-infected with HIV and MDR-TB.

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8 Lessem E et al. An activist's guide to bedaquiline (Situro). New York, NY: Treatment Action Group; 2013.

9 DR-TB drugs under the microscope: sources and prices for drug-resistant tuberculosis medicines. Lausanne and Paris: Médecins Sans Frontières Access Campaign and International Union Against Tuberculosis and Lung Disease; 2013.

10 See Prescribing Information at [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2012/204384s000lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/204384s000lbl.pdf) (accessed 31 December 2013).

### 3. BEDAQUILINE: THE PATENT LANDSCAPE

The patent landscape in Annex I of this report sets out the key patents and patent applications for bedaquiline, including their geographical patent coverage, as of June 2011. While every effort has been made to obtain comprehensive and accurate information on the status and geographical scope of the patents covering bedaquiline, in many countries patent information is not readily available to the public or not updated on a regular basis. In addition, some patent applications may have been published only after the searches were conducted. As such, there may be other relevant patents which have subsequently been published and which are not included in this landscape. Accordingly, the information provided herein is subject to the above disclaimers.

Patent searches revealed five key patents. For ease of reference these five patents have been identified as Patents 1–5 in Annex I. A number of other patents related to substituted quinoline derivative compounds were also identified, but none appear to cover bedaquiline specifically. All the patents were filed and remain in the name of J&J's subsidiary, Janssen Pharmaceutica.

**Patent 1** covers the base compound of bedaquiline. This patent, if granted, serves as a blocking patent preventing any other competitor from making the product. On the basis of available information, Patent 1 appears to have been filed in all high-burden TB and MDR-TB countries. Patent 1 has already been granted in a number of countries, including Armenia, Azerbaijan, Belarus, Bulgaria, China, Estonia, India, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Moldova, Russia, South Africa, Tajikistan and Ukraine, as well as the African Organization of Industrial Property (OAPI) (covering Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo, Côte d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea-Bissau, Mali, Mauritania, Niger, Senegal and Togo).

**Patent 2** claims a method for using bedaquiline for the preparation of a medicament to treat drug-resistant mycobacteria, in particular MDR-TB. In patent parlance, this patent would be referred to as a “method of use patent”. The geographical coverage for this patent is much the same as that for Patent 1. Countries where Patent 2 has been granted include Armenia, Azerbaijan, Belarus, Bulgaria, Estonia, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Moldova, Philippines, Russia and Tajikistan, as well as the African Regional Intellectual Property Organization (ARIPO) (covering Botswana, Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe).

**Patent 3** is a “method of use patent” where bedaquiline is used to treat latent TB. The geographical coverage is much the same as for Patents 1 and 2. The information available indicates that this patent has already been granted in Armenia, Azerbaijan, Belarus, Bulgaria, Estonia, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Moldova, Russia and Tajikistan.

**Patent 4** relates to a process that is used to prepare bedaquiline. Little information relating to the status of this patent was available at the time of the search. Where information was available, it was found that the patent had not as yet been granted in any countries with a high burden of TB and/or MDR-TB. However, the patent has been applied for in a number of these countries.

**Patent 5** covers the end pharmaceutical formulation that will be marketed should bedaquiline be approved. The patent claims the fumarate salt of the enantiomer of bedaquiline. In terms of importance, this patent is second to Patent 1. Given that the international application for this patent was filed in December 2007, at the time of the search many of the applications were pending or the related national phase information had not yet been published by the respective national patent offices. As a result, it may still take some time before a more complete landscape for this patent will emerge.

### 4. CONCLUSION

As this analysis shows, patent applications for bedaquiline have been filed widely, including in countries with a high burden of MDR-TB and DS-TB. While not all the patent applications identified may be pursued and/or granted, this nevertheless indicates that patents are becoming more important in determining access to TB treatment.

Determining the patent situation is a useful starting point for understanding the possible access issues, since patents can bar competitors from manufacturing, selling, importing or exporting a product.<sup>11</sup> Moreover, although only a granted patent can actually bar competition, patent applications serve as a deterrent.

Nevertheless, a patent-holder may choose to implement an access programme and/or to grant licences. As mentioned, Janssen reportedly has agreed to establish an access programme for bedaquiline in relation to MDR-TB, though at the time of writing no details about the access plan were publicly available. However, it is understood that Janssen is working with an Indian manufacturer to produce both the active pharmaceutical ingredient and the final formulation for bedaquiline in order to keep the costs of development and production down.<sup>12</sup>

With respect to the development of bedaquiline for DS-TB by the TB Alliance, it is understood that the project is currently in Phase II.<sup>13</sup> It is currently not clear whether the bedaquiline product being developed by the TB Alliance for DS-TB will have the same dosage as that for MDR-TB. If the two products have the same dosage, separating the markets for these two products could be challenging.

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<sup>11</sup> Companies typically file their patents in a manner that enables them to control access to a drug in key developing-country markets, but also where there is a risk of generic competitors being able to locally produce the drug.

<sup>12</sup> See note 5, above.

<sup>13</sup> Stop TB Partnership Working Group on New TB Drugs. Drug pipeline: bedaquiline (TMC207) for DS-TB. Geneva: Stop TB Partnership; 2013 (<http://www.newtbdrugs.org/project.php?id=125>, accessed 31 December 2013).



## ANNEX I: BEDAQUILINE PATENT LANDSCAPE

	Patent 1	Patent 2	Patent 3	Patent 4	Patent 5
	<p><b>Substituted quinoline derivative compounds, including the free base, enantiomers and isomers of bedaquiline</b></p> <p><i>(This patent includes the base compound bedaquiline with antimycobacterial properties and blocks all manufacturing of the product if granted)</i></p>	<p><b>Use of substituted quinoline derivative compounds for the treatment of drug-resistant mycobacterial diseases</b></p> <p><i>(This patent covers the use of bedaquiline for the preparation of a medicament for the treatment of drug-resistant mycobacteria, in particular multidrug-resistant mycobacteria)</i></p>	<p><b>Use of quinoline derivative compounds, including bedaquiline, for the treatment of latent tuberculosis</b></p> <p><i>(This patent covers the use of bedaquiline for the manufacture of a medicament for the treatment of latent tuberculosis)</i></p>	<p><b>Process for preparing the enantiomer form of bedaquiline</b></p> <p><i>(This patent covers a process for the isolation of the enantiomer of bedaquiline from a mixture of stereoisomeric forms by optical resolution)</i></p>	<p><b>Fumarate salt of bedaquiline and the enantiomer of bedaquiline</b></p> <p><i>(This patent covers pharmaceutical compositions/formulations for administration purposes)</i></p>
<b>Applicant</b>	Janssen Pharmaceutica N.V.	Janssen Pharmaceutica N.V.	Janssen Pharmaceutica N.V.	Janssen Pharmaceutica N.V.	Janssen Pharmaceutica N.V.
<b>*International Patent Publication No.</b>	WO 2004/011436	WO 2005/117875	WO 2006/067048	WO 2006/125769	WO 2008/068231
<b>Expected expiry (if granted and not subject to patent term extensions)</b>	18 July 2023	24 May 2025	8 December 2025	22 May 2026	3 December 2027
	<b>PATENT STATUS</b>				
African Regional Intellectual Property Organization (ARIPO) <sup>11</sup>	Pending Pub/App No. AP/P/2005/003210	Granted Patent No. AP2037A Pub/App No. AP/P/2006/003828	Pending Pub/App No. AP/P/2007/004054	NA	Pending Pub/App No. AP/P/200904870
Argentina	Pending Pub No. AR040673 App No. P030102655	Pending Pub No. AR049127 App No. P050102200	Pending Pub No. 051790 App No. P050105140	NA	Pending Pub No. 064149 App No. P070105442
Australia	Pending Pub/App No. 2003262529	Pending Pub/App No. 2005249231	Pending Pub/App No. 2005242138	Pending Pub/App No. 2006251208	Pending Pub/App No. 2007328945

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	Patent 1	Patent 2	Patent 3	Patent 4	Patent 5
Bosnia and Herzegovina	Pending App No. BAP041930	NA	NA	NA	NA
Brazil	Pending Pub/App No. PI0312927-6	Pending Pub/App No. PI0510414-9	Pending Pub/App No. PI0506400	Pending Pub/App No. PI0611166	NA
Canada	Pending Pub/App No. 2493225	Pending Pub/App No. 2566544	Pending Pub/App No. 2529265	Pending Pub/App No. 2606675	Pending Pub/App No. 2668512
Chile	Pending  App No. 2003- 1477	Pending  App No. 2005-1290	NA	NA	Pending  Pub No. 3472207 App No. 20070003472
China	Granted Pat No. 1325475C  Pub No. 1671667 App No. 03817713.7	Pending  Pub No. 1976704 App No. 200580017016.2	Pending  Pub No. 101087608 App No. 20058044797	Pending  Pub No. 101180302 App No. 20068017475	Pending  Pub No. 101547904 App No. 20078044808
	Pending Pub No. 101070304 App No. 2007101070304				
China, Hong Kong SAR	Granted Patent No. 1083496 App No. 06103424.4	NA	NA	NA	NA
	Pending Pub No. 1113795 App No. 08103990				
Croatia	Pending Pub No. P20050045	NA	NA	NA	NA
Egypt	Pending App No. 704/2003	Pending App No. PCT/1106/2006	NA	NA	Pending App No. 2009060824
Eurasian Patent Organization <sup>2</sup>	Granted Patent No. 008937 App No. 20050000257	Granted Patent No. 010651 Pub/App No. 200602260	Granted Patent No. 009779 App No. 20050000802	Pending Pub/App No. 200702611  (Withdrawn from Russia)	Pending Pub/App No. 200970532
European Patent Office <sup>3</sup>	Granted Patent No. EP1527050  App No. 03771115.7	Granted Patent No. E1753427 App No. 05743054.8	Granted Patent No. EP1830850 App No. 050815816	Pending  Pub No. EP1888604 App No. 0755275	Pending  Pub No. EP2086940 App No. 07847697
	Pending Pub No. EP2301544 App No. 10154018.5				

ANNEX I: BEDAQUILINE PATENT LANDSCAPE

	Patent 1	Patent 2	Patent 3	Patent 4	Patent 5
Gulf Cooperation Council <sup>44</sup>	Pending App No. GCC/P/2003/2796	Pending App No. GCC/P/2005/4703	NA	NA	Pending App No. GCC/P/2007/9625
Iceland	Pending App No. 7620	NA	NA	NA	NA
India	Granted Patent No. 236811 Pub/App No. 220/ DELNP/2005	Pending Pub/App No. 6315/DELNP/2006	Pending Pub/App No. 5213/DELNP/2007	Pending Pub/App No. 9746/DELNP/2007	Pending Pub/App No. 1220/MUMNP/2009
Indonesia	Pending Pub No. 042530 App No. W-00200500183	Pending App No. W00200603351	NA	NA	NA
Israel	Pending App No. 166457	Pending Pub/App No. 179630	Pending Pub/App No. 184123	Pending Pub/App No. 186913	NA
Japan	Granted Patent No. 4484703 Pub No. 2006504658 App No. 523812/04	Pending Pub No. 2008500992 App No. 20070513922	Pending Pub No. 2006182755 App No. 20050170052	Pending Pub No. 2008545675 App No. 20080512822	Pending Pub No. 20100511663 App No. 20090539724
Jordan	NA	Pending App No. PA/2005/74	NA	NA	Pending App No. 511/2007
Kosovo	Pending App No. 039	NA	NA	NA	NA
Lebanon	NA	Pending App No. 7229	NA	NA	Granted Patent No. 8103 App No. 8103
Malaysia	Pending App No. PI20032793	Pending App No. PI2205Z432	NA	NA	NA
Malta	Granted Patent No. 1948 App No. 1948	Pending App No. 2795	NA	Granted Patent No. 3504 App No. 3504	NA
Mexico	Granted Patent No. 267497 Pub/App No. PA/A/2005/001052	Pending Pub/App No. PA/a/2006/013888	NA	Pending Pub/App No. 2007014874	Pending Pub/App No. 2009005909
Montenegro	Pending App No. P-92/08	N/A	NA	NA	NA
New Zealand	Granted Patent No. 538391 App No. 538391	Granted Patent No. 550840 App No. 20050550840	Granted Patent No. 555460 App No. 20050555460	Pending Pub No. 563819 App No. 20060563819	Pending Pub No. 576485

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	Patent 1	Patent 2	Patent 3	Patent 4	Patent 5
Norway	Pending App No. 20050476	Pending Pub/App No. 20066041	Pending Pub/App No. 20073823	Pending Pub/App No. 20076542	Pending Pub/App No. 20092535
Organisation Africaine de la Propriété Intellectuelle (OAPI) <sup>55</sup>	Granted Patent No. 13907 App No. 1200500019	NA	NA	NA	NA
Pakistan	Pending App No. 1113/2006	Pending App No. 0467/05	NA	NA	Pending App No. 1403/2007
	Pending App No. 1114/2006				
	Pending App No. 0640/03				
Peru	NA	NA	NA	NA	Pending Pub No. 13502008 App No. 20070171920
Panama	NA	Pending Pub No. 8635201 App No. 20058635201	Pending Pub No. 8654801 App No. 20058654801	NA	Pending App No. 87597
Philippines	Pending App No. 1-2005-500234	Granted Patent No. 1-2006-502051 Pub/App No. 1-2006502051	NA	NA	Pending App No. 1-2009-500858
Poland	Pending App No. P375523	NA	NA	NA	NA
Republic of Korea	Granted Patent No. 100733577 App No. 10-2005-7000447	Pending Pub/App No. 10-2006-7024974	Pending Pub No. 20060073416 App No. 20050049439	Pending Pub No. 20080010453 App No. 20077028419	Pending Pub No. 20090087020 App No. 20097011043
Serbia	Pending App No. P-58/05	Granted Patent No. 50585 App No. 20080291	NA	NA	NA
Singapore	Granted Patent No. 109784 App No. 200500375-1	Pending App No. 200607882-6	NA	Pending Pub No. 162724 App No. 20100003636	NA
South Africa	Granted Pat No. 2005/0680 App No. 2005/0680	Pending Pub/App No. 200609899	Pending Pub/App No. 200705160	NA	NA

	Patent 1	Patent 2	Patent 3	Patent 4	Patent 5
Sri Lanka	Pending App No. 13575	Pending National Phase App No. N/A	NA	NA	NA
Taiwan, China	Pending Pub No. 200410939 App No. 92120160	Pending App No. 94117334	NA	NA	NA
Thailand	Pending Pub No. 78309 App No. 083992	Pending App No. 100917	NA	NA	NA
Ukraine	Granted Patent No. 82198 App No. 200501778	Pending App No. a200611048	NA	NA	NA
Uruguay	NA	NA	NA	NA	Pending Pub/App No. 30762
USA	Granted Patent No. 7498343 Pub No. 20050148581 App No. 11/007026	Pending Pub No. 20070249667 App No. 11/569,681	Abandoned Pub No. 20060142279 App No. 11/296,992	Abandoned Pub No. 20080200683 App No. 11/915,204	Pending Pub No. 20100028428 App No. 12/515,986
		Pending Pub No. 20100168133 App No. 12/719,221			
Venezuela	NA	Pending App No. 2005-001056	NA	NA	Pending App No. 2007-002659
Viet Nam	Pending App No. 1-2004-01363	Pending App No. 1-2006-01723	Pending App No. 1200701233	Pending App No. 1-2007-02216	Pending App No. 1-2009-0771

\* International applications for patents 1–5 designate all the countries listed below for the African Regional Intellectual Property Organization, Eurasian Patent Organization, European Patent Office and Organisation Africaine de la Propriété Intellectuelle, as well as the following: Algeria, Antigua and Barbuda, Australia, Barbados, Belize, Bosnia and Herzegovina, Brazil, Canada, China, Colombia, Costa Rica, Croatia, Cuba, Democratic People's Republic of Korea, Dominica, Ecuador, Georgia, Grenada, Iceland, India, Indonesia, Israel, Japan, Liberia, Madagascar, Mexico, Mongolia, Morocco, New Zealand, Nicaragua, Norway, Oman, Philippines, Poland, Republic of Korea, Saint Lucia, Saint Vincent and the Grenadines, Seychelles, Singapore, South Africa, Sri Lanka, Trinidad and Tobago, Tunisia, Ukraine, United Arab Emirates, United States of America, Uzbekistan and Viet Nam. Furthermore, some of the international applications designate the following countries: Bahrain (patent 5), Comoros (patents 2–5), Dominican Republic (patent 5), Egypt (patents 2–5), El Salvador (patent 5), Guatemala (patent 5), Honduras (patent 5), Laos (patent 5), Latvia (patents 1–4), Libya (patents 3–5), Malaysia (patent 5), Montenegro (patent 5), Nigeria (patents 2–5), Papua New Guinea (patents 2–5), Saint Kitts and Nevis (patents 3–5), San Marino (patents 2–5), Serbia (patent 5), Syria (patents 2–5).

NA: Patent information not available at the time the patent searches were conducted (June 2011).

<sup>1</sup> African Regional Intellectual Property Organization (ARIPO) patent applications cover the following countries:

Patent 1: Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Sierra Leone, Sudan, Swaziland, Tanzania, Uganda, Zambia and **Zimbabwe**.

Patents 2, 3, 4 and 5: Botswana, Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Sudan, Swaziland, Tanzania, Uganda, **Zambia and Zimbabwe**.

<sup>2</sup> Eurasian Patent Applications cover the following countries:

Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Republic of Moldova, Russian Federation, Tajikistan and Turkmenistan.

<sup>3</sup> European Patent Applications cover the following countries:

Patent 1: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Luxembourg, Monaco, Netherlands, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

Patent 2: as for patent 1, **plus Iceland, Lithuania and Poland**.

**Patents 3–5:** as for patent 1, **plus Iceland, Latvia, Lithuania and Poland**.

<sup>4</sup> Applications at the Patent Office of the Cooperation Council for the Arab States of the Gulf cover the following countries: Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and United Arab Emirates.

<sup>5</sup> Patent applications of the Organisation Africaine de la Propriété Intellectuelle (OAPI) cover the following countries: Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Ivory Coast, Mali, Mauritania, Niger, Senegal and Togo.