

## Intellectual Property Summary

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Rapid Biosensor is building company value by developing strong IP which it plans to exploit commercially by developing a family of medical devices for screening and diagnosis of infectious diseases. Commercial impact and income will be generated from licensing agreements.

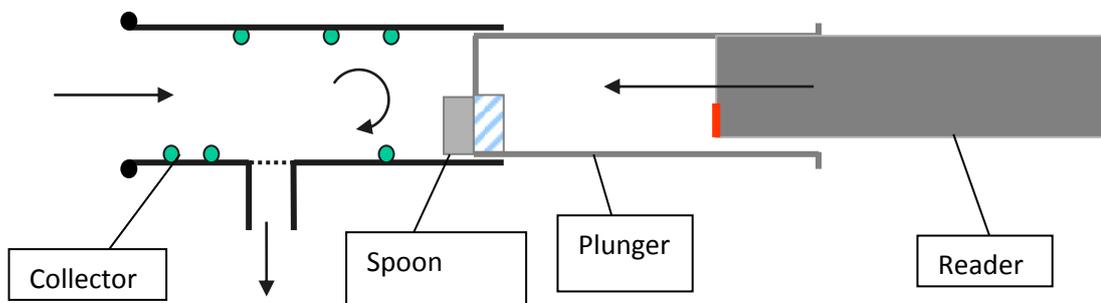
The company has patent protection from comprehensive and robust international patents, prioritised in the major important countries. These comprise:

- **RBS1 - “Biological Measurement System” (PCT WO 02/084266 A2)**
- **RBS 3 - “Bioassay and Peptides for use therein” (PCT WO2007/072063)**
- **RBS 4 – “Measuring Apparatus and Method for Biological Samples” (filed in UK & India, March 2015)**

In detail the patents cover the following areas:

- **RBS1 - “Biological Measurement System” (PCT WO 02/084266 A2):** this is the main device patent and covers the biological measurement system incorporating the collection and analysis of cough samples. It has been granted in Australia, Brazil, Canada, Japan, South Korea, Mexico, South Africa and the USA; pending in the EU. A Divisional, US patent has also been granted which covers liquid sample collection in greater detail.

The patent covers the system and method which is a combination of aerosol cough collection, immunassay systems and detection by evanescent wave fluorimetry. The principle is shown in the figure below, where the cough is collected in a cough tube, the sample is gathered onto the bio-coated surface using a plunger and rotation method, before detection of the reaction on the surface using fluorimetry.





**TB Breathalyser & Reader**

The patent has 21 claims covering extensive additional potential areas of application, sample types (including all bodily fluids,) detection methodologies and target antigens as well as a methodology for easing the production of a cough sample and loosening an antigen for detection.

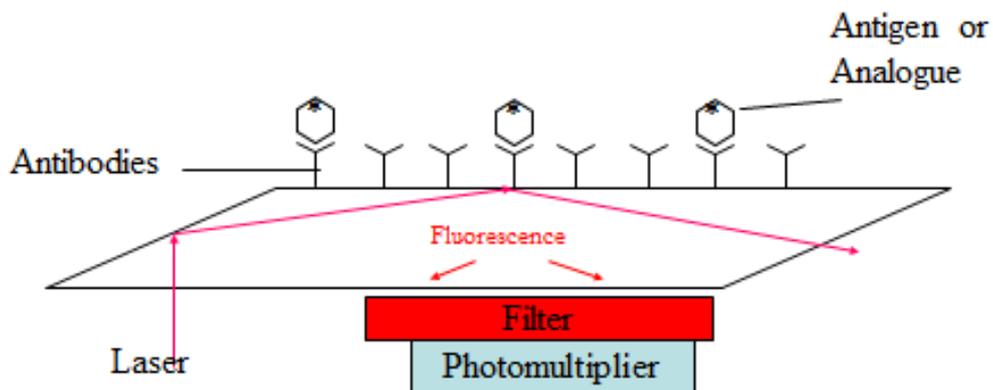


**The Cough tube in use**

**RBS3 - "Bioassay and Peptides for use therein" (PCT WO2007/072063):** this patent covers the analogue and antibody system for the biochemical test performed to detect TB - ie the TB displacement assay system. It has been granted in Australia, Russia, South Africa and the USA; pending in Canada and the EU.

The tests covered in this patent are based on a T-cell epitope from *M. tuberculosis* Ag85B, represented by the 18-mer peptide p3 (Amino acids 19 to 36, denoted P779) with the sequence GRDIKVQFQSGGNNSPAV (SEQ ID 11). The patent covers peptides of fewer than 18 amino acids that are analogues to the T cell epitope and comprise the sequence NSPAX where X is Methionine (SEQ ID 18), Leucine (SEQ ID 17), Alanine (SEQ ID 15) or Valine (SEQ ID 10) where the peptide is capable of binding to an antibody raised against the peptide GRDIKVQFQSGGNNSPAV (SEQ ID 11).

In the Rapid Biosensor MTB system, the antibodies are attached to the surface of a glass prism as shown in the figure below.



The analogue peptides can be fluorescently labelled and bind more weakly to the antibodies than do the TB bacilli themselves, so that when the MTB bacilli are present they displace the analogue. This displacement in the case of the Rapid Biosensor test is in the near surface region of glass prism on which the sample has been collected and so this results in a decrease in the observed fluorescent signal at the surface.

- **New RBS4 - “Measuring Apparatus and Method for Biological Samples” (GB1505477.8 & IN1198/MUM/2015):** this is the latest patent filing which covers the apparatus and method for further developments of the product approach, to encompass wider areas of application and applicability of the techniques; and additional features such as software and data handling by the devices, high cost effectiveness, low power requirements and multiple test capabilities. It has been filed simultaneously in GB and India. PCT publication will be 30 March 2016.

**Current status.**

The following table provides a detailed breakdown of the status of the patents worldwide:

<b>RBS1 - Biological Measurement System</b>						
	Country	Status	Ref	Grant Number	Grant date	Priority date
1	Australia	Granted	2002/253310	2002253310	05/01/2007	11/04/2001
2	Brazil	Granted	PI0210210-2	In process	~ 3/2015	11/04/2001
3	Canada	Granted	2442359	2442359	04/05/2011	11/04/2001
4	Europe	Pending	02 722 430.2			11/04/2001
5	Japan	Granted	2002-581969	7384793	05/09/2008	11/04/2001
6	S Korea	Granted	10-2003-7013064	10-0878093	24/01/2009	11/04/2001
7	Mexico	Granted	PA/a/2003/009111	267257	08/06/2009	11/04/2001
8	S Africa	Granted	2003/7605	2003/7605	11/04/2004	11/04/2001
9	USA	Granted	10/474,877	7384793	10/06/2008	11/04/2001
10	USA Divisional	Granted	10/474,877	8,030,088	04/10/2011	11/04/2001
<b>RBS3 - Bioassay and Peptides for use therein</b>						
1	Australia	Granted	2006327953	526273.8	22/08/2013	23/12/2005
2	Canada	Pending	2634638			23/12/2005
3	Europe	Pending	6831482.2			23/12/2005
4	Russia	Granted	2008130399	2439080	10/01/2012	23/12/2005
5	S Africa	Granted	2008/05343	2008/05343	25/11/2009	23/12/2005
6	USA	Granted	12/158,781	8,372,412	14/02/2013	23/12/2005
<b>RBS 4 - Measuring Apparatus and Method for Biological Samples</b>						
1	GB	App filed	GB1505477.8			30/03/2015
2	India	App filed	IN1198/MUM/2015			30/03/2015

**IP and Product implementation**

	TB Breathalyser Test	Pneumonia Test	Bovine TB Test	Sputum TB Test	TB Bioassay only
RBS1	✓	✓	✓	✓	
RBS3	✓		✓	✓	✓
RBS4	✓	✓	✓	✓	