

# 에볼라와 특허

남희섭

2014. 11. 19.

# US\$ 2.56 billion

Tufts Center for the Study of Drug Development  
November 18, 2014

[Cost to Develop and Win Marketing Approval for a New Drug Is \\$2.6 Billion](#)

## 소외 질병 Neglected Disease

MSF: Regardless of how much R&D costs ...  
there is no treatment or vaccine on the market

WIPO SCP November Kenya delegate for the African Regional Group “Thousands of people are dying, yet this patent system, this organisation who is supposed to cater for our interests does not seem to care.” “If we cannot have a patent system and pharmaceutical industries work for all of us, then let’s not pretend and use the word ‘balance’,”

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Results 51-60 of 249 for Criteria: Office(s):all Language:EN Stemming:true

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Analysis

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No	Ctr	Title	PubDate	Int.Class	Appl.No	Applicant	Inventor
51.	CA	<a href="#">2807136</a> - ANTISENSE ANTIVIRAL COMPOUNDS AND METHODS FOR TREATING A FILOVIRUS INFECTION	16.02.2012	A61K 31/5375	2807136	SAREPTA THERAPEUTICS, INC.	IVERSEN, PATRICK L.

The present invention provides antisense antiviral compounds, compositions, and methods of their use and production, mainly for inhibiting the replication of viruses of the Filoviridae family, including [Ebola](#) and Marburg viruses. The compounds, compositions, and methods also relate to the treatment of viral infections in mammals including primates by [Ebola](#) and Marburg viruses. The antisense antiviral compounds include phosphorodiamidate morpholino oligonucleotides (PMOplus) having a nuclease resistant backbone, about 15-40 nucleotide bases, at least two but typically no more than half piperazine-containing intersubunit linkages, and a targeting sequence that is targeted against the AUG start site region of [Ebola](#) virus VP35, [Ebola](#) virus VP24, Marburg virus VP24, or Marburg virus NP, including combinations and mixtures thereof.

52.	US	<a href="#">20120035136</a> - Antisense antiviral compounds and methods for treating a filovirus infection	09.02.2012	C07H 21/02	12853180	AVI BioPharma, Inc.	Iversen Patrick L.
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**IASR - PCT/US2009/062079**

**HUMAN EBOLA VIRUS SPECIES AND COMPOSITIONS AND METHODS THEREOF**

**Applicant(s): THE GOVERNMENT OF THE UNITED STATES OF AMERICA AS REPRESENTED BY THE SECRETARY, DEPARTMENT OF HEALTH & HUMAN SERVICES, CENTER FOR DISEASE CONTROL AND PREVENTION**

**Abstract:(EN): Compositions and methods including and related to the Ebola Bundibugyo virus (EboBun) are provided. Compositions are provided that are operable as immunogens to elicit and immune response or protection from EboBun challenge in a subject such as a primate. Inventive methods are directed to detection and treatment of EboBun infection.**

## 에볼라 관련 국내 특허 현황

- 246개 특허출원 중에서 WO건(63건)을 제외한 출원은 183건이며, 이 중 25건이 국내 대응출원이 있는 것으로 파악됨
- 상기 25건은 심사 미청구로 취하 간주되거나 등록료 미납에 따라 포기되어 특허권이 설정되지 않았음.
- 63건의 국제출원 중에서 3건이 국내단계에 진입하였으며, 3건 모두 심사 미청구로 취하 간주되어 특허권이 설정되지 않았음.

캐나다(VSV-Evo) 및 GSK 백신(adenovirus EboV-GP)관련 PCT 국제출원(3건)은 대한민국을 지정하였으나, 국내서면제출기간이 경과하여 향후 국내 진입 불가

구분	외국 특허출원 현황	PCT 공개번호 (지정여부)
캐나다 백신 (VSV-Evo)	호주(AU2003250680A1) 캐나다(CA2493142A1) 독일(DE60330966D1) 유럽(EP1527087A2, EP1527087B1, EP1527087B2) 스페인(ES2338416T3, ES2338416T5) 미국(US8012489B2, US20060193872A1)	WO 2004/011488 (지정)
	미국(US20050255123) 호주(AU2003232004)	WO/2003/092582 (지정)
GSK 백신 (adenovirus EboV-GP)	유럽(EP2560680A2), 미국(US20130101618)	WO 2011/130627 (지정)

## 에볼라 바이러스에 대한 미국 정부의 특허

- PCT 출원(국제출원번호 PCT/US2009/062079, 국제공개번호 WO 2010/048615)는 국내단계에 진입하지 않았으며, 국내서면제출기간이 경과하여 향후 국내 진입 불가
- 해당 출원은 캐나다, 유럽특허청, 인도 및 미국에만 국내단계 진입



- 에볼라 바이러스에 효과를 보이는 백신은 1건, 치료제는 3건 특허출원되었으며, 에볼라 바이러스 자체에 대한 특허출원은 없음
- 4건의 특허출원 중에서 1건이 심사청구되었으며 2013년 11월에 특허등록되었음(등록번호 제10-1329878호)

구분	출원번호 (출원인 국적)	공개번호	심사진행현황	출원인/권리자
백신	10-2013-7016833 (미국)	10-2014-0019304	심사미청구	미국 정부
치료제	10-2007-7020614 (중국)	10-2007-0108904	특허등록	"위 광원" (중국 스촨시)
치료제	10-2012-7007711 (미국, 영국)	10-2012-0081990	심사미청구	더 찬슬러 마스터즈 앤드 스칼라스 오브 더 유니버시티 오브 옥스포드
치료제	10-2013-7012318 (미국)	10-2014-0040676	심사미청구	바이오크리스트파마슈티 컬즈,인코포레이티드

# 특허 문제

- ❑ It seems legitimate to wonder if intellectual property rights on the virus or its treatments would constitute a barrier to availability of those treatments in poor countries directly affected by this neglected tropical disease.
- ❑ two WHO IP specialists, “at the moment, the barrier to access of any of the experimental Ebola treatments is not intellectual property.”
- ❑ 의약품 출시보다 특허권 취득 경쟁에 많은 투자
- ❑ 대량생산 공급 단계가 되면 수면 위로 올라올듯.

# 자료독점권

- ❑ 한미 FTA, 한-EU FTA
- ❑ 신약: 5년, 새로운 효능: 3년
- ❑ 의약품의 품목허가·신고·심사 규정 제27조 제8항 “동등범위 이상의 자료”를 제출하지 않으면 재심사기간(신약 6년, 새로운 효능 4년)
- ❑ 예외는 2가지 뿐임
  - 최초허가자 또는 원개발사로부터 자료사용이 허용된 경우
  - [제25조제2항](#) 제8호에 해당하는 의약품으로서 재심사 기간 종료 후 품목허가 받을 것을 조건으로 신청하는 경우

## TPP

**Article QQ.E.20:** With respect to the first marketing approval of a pharmaceutical product that is biologic,<sup>[231](#)</sup> each Party shall provide the protection afforded under Article QQ.E.16.1(a)-(b), *mutatis mutandis* for a period of [0] / [5] / [8] / [12] years from the date of marketing approval of such pharmaceutical product in that Party.

# DISCUSSION