

FACT SHEET **Insulin Patent Profile**

The *Insulin Patent Profile*, published in April 2016, contributes to a better understanding of whether patents could be a barrier to access to insulin. This fact sheet provides an overview of the key findings of this research. Publicly-accessible databases from the US, European, Chinese and Indian patent offices, and the US Food and Drug Administration (Orange Book) and Health Canada, were reviewed to determine the patent status of human and analogue insulins. The profile and related fact sheet is the result of the mapping work completed in phase one of the Addressing the Challenge and Constraints of Insulin Sources and Supply (ACCISS) Study and is one of several

profiles on the global insulin market to be published.

The Leona M. and Harry B. Helmsley Charitable Trust and Stichting ICF are funding the ACCISS Study. The analysis included in this fact sheet is that of the authors alone and does not necessarily reflect the views of the Helmsley Charitable Trust or Stichting ICF. All references and conclusions are intended for educational and informative purposes and do not constitute an endorsement or recommendation from the Helmsley Charitable Trust or Stichting ICF.

All profiles and fact sheets can be accessed on the ACCISS Study section of HAI's website: <http://haiweb.org/what-we-do/acciss/>

Please note, all references in this fact sheet come directly from the Insulin Patent Profile.

Access to Insulin in the Spotlight



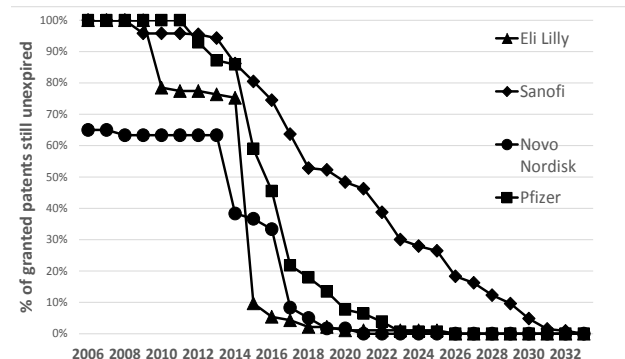
Patents on Insulin Products Already on the Market

- There are no patents on any formulations of human insulins.
- Based on the filing date and a 20 year patent period, patents on analogue insulins already on the market in the US and Canada have expired or will soon expire in these countries and elsewhere (Figure 1).
- Four companies, Eli Lilly, Sanofi, Novo Nordisk, and Pfizer, own these patents.
- The patents were most commonly filed in North America, Europe, Australia, and China.

Patents on Insulin in Development

- Across the four companies, the patent expiration dates of insulins in development are generally later than those of insulin products already on the market. Any insulin patents that might eventually be granted will expire as late as the 2030's (Figure 2).
- The patents and patent applications were filed in more regions of the world compared to the filings of insulin products already on the market.

Figure 1



Other Insulin Manufacturers

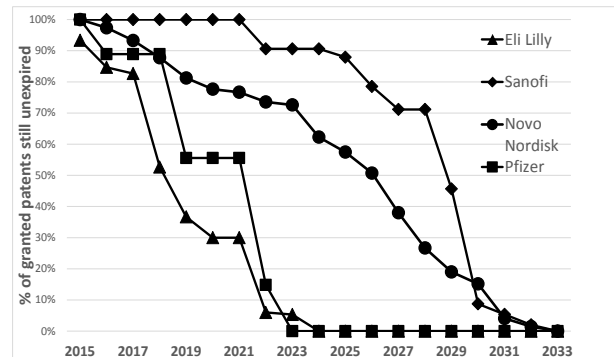
- Patent applications for insulin were found for only four other companies: Biocon and Wockhardt (India), and Tonghua Dongbao, and Zhuhai United Laboratories (China).

Recent work by Luo and Kesselheim in *The Lancet Diabetes & Endocrinology* on this topic in the US highlighted¹:

- 19 active patents on insulin in 2014 with 10 of these filed by Novo Nordisk, six by Sanofi, and three by Eli Lilly.
- More than half of patents were for insulin-containing devices rather than the active ingredient. (See also reference 2).
- At the end of 2015, there will be no patent protection on 11 common insulin products sold in the US.
- Intellectual property cannot be seen as a barrier to entry for biosimilar manufacturers.

1. Luo J, Kesselheim AS. Evolution of insulin patents and market exclusivities in the USA. *The lancet Diabetes & endocrinology*. 2015 Nov;3(11):835-7. PubMed PMID: 26453281.
2. Beall RF, Nickerson JW, Kaplan WA, Attaran A (2016) Is Patent "Evergreening" Restricting Access to Medicine/Device Combination Products? *PLoS ONE* 11(2): e0148939. doi:10.1371/journal.pone.0148939

Figure 2



This data confirms that for insulin products already marketed, the expiration of key patents on analogues has already taken place or will soon take place (albeit some patents filed by Sanofi have later expiration dates than their competitors). A different picture is seen for insulin in development where there is no obvious patent cliff. Patents, if granted, will extend into the future particularly for Novo Nordisk and Sanofi products. Of concern should be the increase in patents on devices, which might tie individuals to cer-

tain types of insulin. That said, unlike other medicines where intellectual property could be seen as a barrier to access this is not the case for human insulin.

Certain limitations in the search methodology should be noted, including the exclusion of products marketed outside of North America. Additionally, publicly disclosing patent information with Health Canada is optional and listing patents may be delayed as they first screen and review them.