



(12) Translation of  
European patent specification

(11) NO/EP 3045471 B1

NORWAY

(19) NO  
(51) Int Cl.  
**C07K 14/59 (2006.01)**  
**A61K 38/00 (2006.01)**  
**A61K 38/24 (2006.01)**

**Norwegian Industrial Property Office**

---

|      |                                                                      |                                                                                                                                                                                                                                                                                             |
|------|----------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (21) | Translation Published                                                | 2017.07.10                                                                                                                                                                                                                                                                                  |
| (80) | Date of The European Patent Office Publication of the Granted Patent | 2017.03.29                                                                                                                                                                                                                                                                                  |
| (86) | European Application Nr.                                             | 16158141.8                                                                                                                                                                                                                                                                                  |
| (86) | European Filing Date                                                 | 2009.04.16                                                                                                                                                                                                                                                                                  |
| (87) | The European Application's Publication Date                          | 2016.07.20                                                                                                                                                                                                                                                                                  |
| (30) | Priority                                                             | 2008.04.25, EP, 08251528<br>2008.04.16, US, 45424 P                                                                                                                                                                                                                                         |
| (84) | Designated Contracting States:                                       | AT BE BG CH CY CZ DE DK EE ES FI FR GB GR<br>HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL<br>PT RO SE SI SK TR                                                                                                                                                                              |
| (73) | Proprietor                                                           | Ferring B.V., Polaris Avenue 144, 2132 JX Hoofddorp, NL-Nederland                                                                                                                                                                                                                           |
| (72) | Inventor                                                             | COTTINGHAM, Ian, Ferring International Center S.A.Ch. de la Vergognausaz 50, 1162 Saint-Prex, CH-Sveits<br>PLAKSIN, Daniel, Ferring International Center S.A.Ch. de la Vergognausaz 50, 1162 Saint-Prex, CH-Sveits<br>WHITE, Richard, Boyd, 1348 Sutter Street, San Diego, CA 92103, US-USA |
| (74) | Agent or Attorney                                                    | Oslo Patentkontor AS, Postboks 7007 Majorstua, 0306 OSLO, Norge                                                                                                                                                                                                                             |

---

|      |       |                                                                       |
|------|-------|-----------------------------------------------------------------------|
| (54) | Title | <b>RECOMBINANT FSH INCLUDING ALPHA 2,3- AND ALPHA 2,6-SIALYLATION</b> |
|------|-------|-----------------------------------------------------------------------|

|      |                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|------|-------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (56) | References Cited: | WO-A-03/035686<br>WO-A1-2012/016576<br>FLACK M R ET AL: "Increased biological activity due to basic isoforms in recombinant human follicle-stimulating hormone produced in a human cell line.", THE JOURNAL OF CLINICAL ENDOCRINOLOGY AND METABOLISM SEP 1994, vol. 79, no. 3, September 1994 (1994-09), pages 756-760, XP002494715, ISSN: 0021-972X<br>HORSMAN G ET AL: "A biological, immunological and physico-chemical comparison of the current clinical batches of the recombinant FSH preparations Gonal-F and Puregon", HUMAN REPRODUCTION 2000 GB, vol. 15, no. 9, 2000, pages 1898-1902, XP002494716, ISSN: 0268-1161<br>DICKY RICHARD P ET AL: "Highly purified human-derived follicle-stimulating hormone (Bravelle(R)) has equivalent efficacy to follitropin-beta (Follistim (R)) in infertile women undergoing in vitro fertilization", REPRODUCTIVE BIOLOGY AND ENDOCRINOLOGY, BIOMED CENTRAL LTD, GB, vol. 1, no. 1, 3 October 2003 (2003-10-03) , page 63, XP021009333, ISSN: 1477-7827, DOI: 10.1186/1477-7827-1-63<br>OLIJVE W ET AL: "Molecular biology and biochemistry of human recombinant follicle stimulating hormone (Puregon).", MOLECULAR HUMAN REPRODUCTION MAY 1996, vol. 2, no. 5, May 1996 (1996-05), pages 371-382, XP002494717, ISSN: 1360-9947<br>JONES D ET AL: "High level expression of recombinant IgG in the human cell line PER.C6", BIOTECHNOLOGY PROGRESS, XX, XX, vol. 19, 1 January 2003 (2003-01-01), pages 163-168, XP002256988, ISSN: 8756-7938 |
|------|-------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|



Enclosed is a translation of the patent claims in Norwegian. Please note that as per the Norwegian Patents Acts, section 66i the patent will receive protection in Norway only as far as there is agreement between the translation and the language of the application/patent granted at the EPO. In matters concerning the validity of the patent, language of the application/patent granted at the EPO will be used as the basis for the decision. The patent documents published by the EPO are available through Espacenet (<http://worldwide.espacenet.com>) or via the search engine on our website here: <https://search.patentstyret.no/>

**Patentkrav**

1. Fremgangsmåte ved fremstilling av rFSH som omfatter  $\alpha$ 2,3- og  $\alpha$ 2,6-sialylering, hvilken fremgangsmåte omfatter et trinn med å fremstille eller uttrykke rFSH i en Per.C6-cellelinje; hvor Per.C6-cellelinjen er blitt konstruert for å uttrykke et  $\alpha$ 2,3-sialyltransferase.
- 5 2. Fremgangsmåte ifølge krav 1, hvor Per.C6-cellelinjen har endogen  $\alpha$ 2,6-sialyltransferaseaktivitet.
3. Fremgangsmåte ifølge krav 1 eller 2, hvor 10% til 90% av den samlede sialylering er  $\alpha$ 2,3-sialylering.