The experience of the University of Foggia: Method for the detoxification of gluten proteins from grains of cereals.

Technology and Patent Development Strategy

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Development Strategy of the Invention

Italian patent granted as n. 0001414717 titled "Metodo per la detossificazione delle proteine del glutine dalla granella di cereali" (priority filing ITRM20120468)

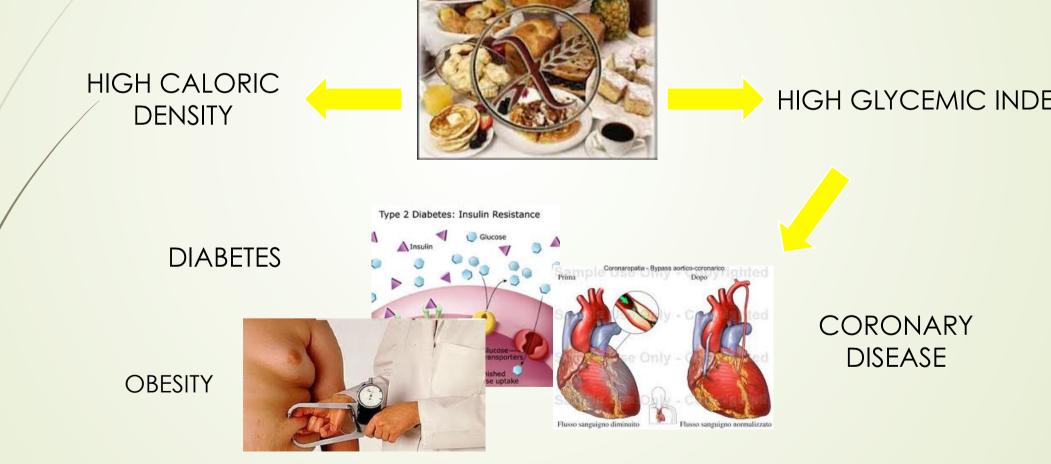
Request for extension n. PCT/IB2013/000797 titled "Method for the detoxification of gluten proteins from grains of cereals"

Strategy goals

- Diffusion of the technology (maximum impact)
- Exploitation strategy consistent with the public nature of the University of Foggia and there source of funding (taxpayers)
- Several model(s) of exploitation available (at least in theory)

State of the art

GLUTEN FREE FOOD



Weaknesses and Threats

- a. patent costs (related to the geographic coverage)
- b. uncertainty about the toxicological profile (technological risk)
- c. limited knowledge about the scalability of the detoxification process (industrial risk)
- d. need for capital
- e. need for industrial expertise for a credibile valorization strategy
- f. social acceptance of radical innovation

Strengths and Opportunities

- a. extremely good quality of patent protection and large geographical coverage
- b. at least one collaborative industrial partner
- c. one proactive and collaborative inventor (lately founder of the spin-off)
- d. relatively mature technology
- e. huge market opportunity and perceived social need

International search report PCT/IB2013/000797

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1.	Statement			
	Novelty (N)	Yes:Claims	1-14	\mathcal{I}
		No: Claims		
	Inventive step (IS)	Yes:Claims	1-14	\supset
		No: Claims		
	Industrial applicability (IA	Yes:Claims	<u>1-14</u>	\supset
		No: Claims		

Technological properties of the method

DETOXIFIED SEMOLINA



DOUGH FORMATION DETOXIFIED GLUTEN



CONTROL SEMOLINA



CERMIROIN & DUTENCH



Requirements for a possible path of exploitation

- a. Neminem laedere (technological risk, again)
- b. Limit the liability of each party involved (particularly UNIFG)
- c. Ensure maximum market penetration of the technology (for a huge market)
- d. Access to the right level of the value chain (who is the «end»-user of the technology?)
- e. Avoid depletion of technology (strenghtening the position of the patent owner)
- f. Have resources for monitoring the market

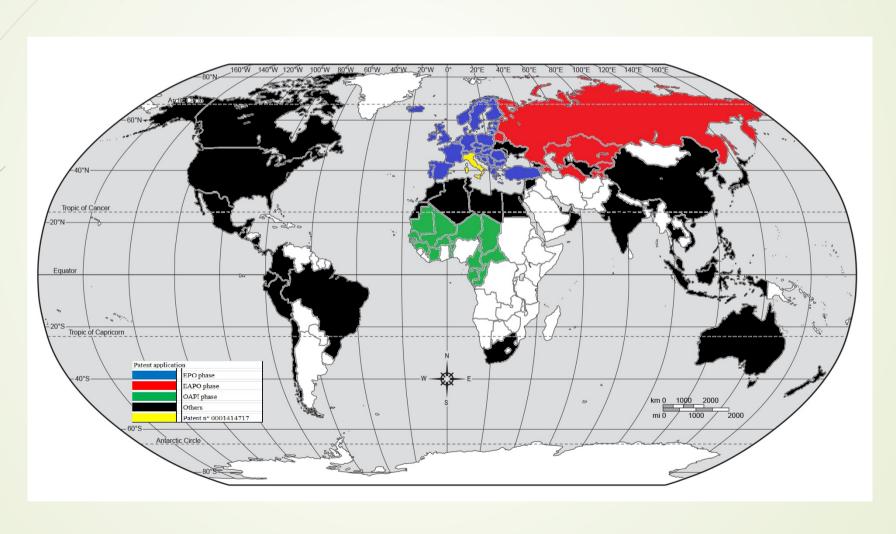
Outlines of a possible strategy

- a. Increase the added value of the invention (no "bread-and-butter" deal)
- b. A possible path of exploitation
- c. make sure not to make mistakes along the road
- d. review strategy and consider chock-points

a. Increase the added value of the invention (for package licensing)

- i. Certification of the process (cooperation with Reding University for ex vivo studies)
- ii. International branding (a strong and distinctive international trademark associated to the use of technology)
- iii. Guidelines for detoxification as complementary know-how (licensed in a bundle)
- Iv. Complementary know-how related to the industrial scale-up
- iv. The educational program for the Made in Italy Made-in UNIFG New Gluten World.

Patents application in the world (PCT/IB2013/000797). Current patent coverage



b. A possible path of exploitation

- i. Forming a spin-off company (not just moving away from the TTO)
- ii. The involvement of a partner (industrial v. financial)
- iii. License between UNIFG and the spin-off (also for improvements of the technology)
- iv. The B2B license agreement between the spin-off and the producers and the Worldwide "Gluten Friendly" Licensing Program

i. Forming a spin-off company

Essential features:

- Streamlined structure
- Professional management
- (Not invasive) participation of UNIFG
- Advisory board
- Shield of responsibility
- Configuration as innovative start-up (pursuant to Italian Decreto Crescita 2.0)
- Limitation to the share of the industrial partner (to keep the quality of small and medium enterprise)

ii. The involvement of an industrial partner

Necessary for 3 reasons:

- (i) To complete the commercialization phase
- (ii) To bring the necessary expertse for commercialization and knowledge of the market
- (iii) Provide the financial resources to give the spin-off the opportunity to achieve its objectives

iii. License between UNIFG and the spin-off

- Exclusive, field-of-use license for flour detoxification
- Royalty-bearing license
- Right to sub-license to 3rd parties
- Empowerment of the Worldwide (Gluten Friendly) Licensing Program

iv. The B2B license agreement between the spinoff and the producers and the "Gluten Friendly" Licensing Program

Characteristics of the final license managed by the spin-off:

- Exclusive limited to some territories
- Royalty-bearing, based on the intensity of exploitation (quintals of detoxified flour as royalty base)
- Additional obligations of compliance to the guidelines
- Obligations of absolute confidentiality of the transferred know-how to licensee
- Grant back licenses obligations in case of improvements resulting from the application process by licensees
- No-challenge clause for licensees

Q&A Thank you