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Nota di contenuto	Cover; I. INTRODUCTION; A. Overview; B. Outline of the dissertation; C. Scope of the dissertation; II. PHARMACEUTICAL INVENTIONS, INNOVATIONS & PRODUCTS; A. Cumulative nature of inventions; 1. Basic and second generation inventions; a) Improvement inventions; b) Selection inventions; B. Inventions and innovations in pharmaceutical field; 1. Inventions and patents in pharmaceutical field; a) Product invention and the absolute character of its protection; b) Hierarchy of pharmaceutical patents; 2. Innovations in pharmaceutical field; a) Invention v. innovation b) NMEs as the core of pharmaceutical innovation C. Second generation inventions and patents in pharmaceuticals; 1. Product inventions and patents; a) Species selection inventions; Markush type claim; A species claim; b) Optical isomers; c) Crystalline forms; d) Metabolites and prodrugs; e) Esters and salts; f) Dosage forms; g) Combinations of active ingredients; 2. Use inventions; a) New Use/New method of treatment; b) Dosage regime; 3. Process inventions; a) Process; b) Intermediates; D. Pharmaceutical products in the market 1. New medical entities, new molecular entities 2. Similar or equivalent

"me-too" products; 3. Second generation products; 4. Generic drugs; E. Summary; III. SPECIFICITIES IN PHARMACEUTICALS AND RECENT DEVELOPMENTS; A. Innovating and inventing in pharmaceutical industry; 1. Specificities in the drug development process; a) Highly regulated industry; b) R&D - a costly and lengthy road to a medicine; c) Uncertainties in post-invention development; (1) Scientific uncertainty: Unpredictability of substances; (2) Regulatory and market uncertainties; d) Information rich chemicals
2. Specificities in the market for pharmaceuticals a) Imitation with negligible cost and much reduced risk; b) Prescription based purchase: A disconnection between choosers and payers; c) Information asymmetry and high loyalty to a medicine; d) Pricing; 3. Specificities of the patent protection for pharmaceuticals; a) Patent protection for industrial technologies; b) Patent protection in the pharmaceutical industry; B. Challenges and overcoming efforts; 1. Decreased R&D productivity; 2. Dearth of new medical entities; a) Significance of NMEs; b) Decreased number of NMEs
c) Potential reasons for the decrease (1) Decrease in solvable scientific problems; (2) Stringent safety regulations; (3) Problem of over-disclosure; (4) Early and numerous abandonments of potential candidates; 3. Patent cliffs of blockbuster medications; 4. Frequent merger and acquisitions (M&As) and in-licensing; 5. Drastic increase of second generation inventions; a) Life cycle management or evergreening; b) Drastic increase of this activity supported by the number of second generation patents; C. Summary; IV. STANDARDS OF PATENTABILITY FOR PHARMACEUTICAL SELECTION INVENTIONS
A. Novelty and anticipation

Sommario/riassunto

Die Entwicklung neuer Medikamente und deren Verbesserungen sind entscheidend, um deutliche Fortschritte in der Gesundheitsversorgung zu gewährleisten. Der Entwicklungsprozess ist lang und teuer, insbesondere der Aufwand, der betrieben werden muss, um den hohen Regulierungsanforderungen gerecht zu werden. Im Gegensatz dazu verursacht die Nachahmung von Medikamenten vernachlässigbare Kosten und birgt deutlich weniger Risiken. Dies ist einer der Gründe, warum der Patentschutz für die pharmazeutische Industrie von so großer Bedeutung ist. Trotz des bestehenden Patentsystems i
