International Journal of Scientific Research Updates

Journal homepage: https://orionjournals.com/ijsru/

ISSN: 2783-0160 (Online)

(REVIEW ARTICLE)

Cancer-related innovation and U.S. patent applications

Michael John Dochniak * and Christian James Glancey

Alleamit Corporation, Minnesota, USA.

International Journal of Scientific Research Updates, 2022, 04(02), 191–194

Publication history: Received on 22 October 2022; revised on 22 November 2022; accepted on 25 November

2022 Article DOI: https://doi.org/10.53430/ijsru.2022.4.2.0182

Abstract

Cancer therapies bring hope to the suffering and dying patient. However, cancer research is complex and expensive. In addition, cancer is not just one disease but many. Each with its characteristics, risk factors, causes, and treatments—currently, 35 U.S. Code § 103 (obviousness) rejections are a rate-limiting step for acquiring a patent. Unfortunately, rejecting novel cancer-related patent applications based on obviousness inhibits funding for much-needed drug development and research.

Keywords: Cancer; Drugs; Funding; Obviousness; Patents; Research

1 Introduction

There are many types of cancer without effective treatment [1]. Each year in the United States, more than 1.7 million people are diagnosed with cancer, with approximately 600,000 deaths, making it the nation's second leading cause of death [2].

Cancer research is costly. Billions of dollars bring candidate cancer medications through the testing and verification process. The median approval cost of a single cancer drug exceeds $1.6 billion [3].

Patents play a critical role in drug development for cancer research. The United States Patent and Trademark Office (USPTO) is a fee-funded agency of the U.S. Department of Commerce. One function of the USPTO is to grant patents to protect inventions [4]. A patent is an exclusive right to a product or a process that generally provides a new way of doing something or offers a new technical solution to a problem. For acceptance, the patent makes unique information public [5]. This sharing of information expands knowledge to effect continuous improvement.

2 Discussion

Patented medications are a big business. Patents provide a 20-year monopoly right, during which a pharmaceutical company enjoys market exclusivity and can charge a monopoly price for its products. Originators argue that strong patent protection is essential to recoup investments and incentivize them to engage in further innovation [6]. Once a patent expires, the protection ends, and the disclosed innovation enters the public domain; anyone can commercially exploit the invention without infringing the expired patent.

A study on drug revenue trends among major pharmaceuticals indicates that annual revenue generated from cancer drugs increased by 70%: From $55.8 billion to $95.1 billion. In comparison, income from non-oncology medications decreased by 18%: from $342.2 billion to $281.5 billion [7].

* Corresponding author: Michael John Dochniak
Alleamit Corporation, Minnesota, USA.

Patents encourage investors to fund drug development for cancer research [8]. The National Institute of Health, major pharmaceuticals, small business entities, and micro-entities understand that patents are essential to funding drug development for cancer research. The technology transfer center at the National Cancer Institute discusses the value and process of cancer-related patents [9].

Patent applications are expensive. For example, preparing and filing a non-provisional utility patent application can cost $20,000. Prices vary depending on the law firm and the complexity of the invention. In addition, during the patent process, there will be attorney's fees and other additional costs related to the application's examination. As a result, the final price can be more than $100,000 [10].

The USPTO has attempted to assist cancer-related applications through a new program titled *Patents 4 Patients*. This program provides a fast-track review for cancer immunotherapy patent applications. Under this program, applications are advanced out of turn for examination, resulting in accelerated review. *Patents 4 Patient***s** cut the time it takes to review patent applications in half, issuing final decisions in one year or less after receiving them [11].

Gaudry and Rothwell write that conquering cancer remains a national priority. However, one of the most significant contributions that the USPTO could provide is to address an issue that affects a group of innovators by improving examination variability and uncertainty. The type of rejection the Examiner applies to the patent application can affect its outcome. The USPTO allows the Examiner to reject novel cancer-related patent applications based on a *35 U.S. Code § 103* obviousness rejection. Under *35 U.S. Code § 103*, a patentable invention must be a non-obvious improvement over the prior art; thus, a rejection under this section means the Examiner considers the invention obvious. However, a *35 U.S. Code § 103* obviousness rejection can be problematic. The prior art that allegedly teaches the innovation at issue is not disclosed in a single reference but inferred from a combination of previous art references. An obviousness determination, then, is intensely subjective. The USPTO reconciles this by using a reasonable person standard. Would a person of ordinary skill in "the art" have found the idea obvious? Even when courts use this standard, however, there can still be room for debate as to what "ordinary skill" in a particular art means. *35 U.S. Code § 103* obviousness rejections are likely the most common first final rejections for these reasons—obviousness determinations are subjective, and reasonable minds can easily disagree on their outcome [12].

Those skilled in patent drafting (e.g., patent attorneys and agents) often throw the “proverbial” kitchen sink into the specification. This wordplay strengthens patent claims through the doctrine of equivalence (DOE). The DOE is a means by which a patent holder may raise a claim of infringement even though each element of the patented invention is not identically present in the allegedly infringing product or process [13]. Unfortunately, an experienced patent Examiner can randomly combine the information in multiple references and apply a 35 U.S *Code § 103* rejection to future patent applications.

At the USPTO, patent Examiners in the Art Unit 1699 (Drug, bio-affecting, and body treating compositions) have a 3-year grant rate of approximately 60%. The overall 3-year grant rate at the USPTO is 73% [14]. In an analysis to determine which rejection type was most likely to affect your next application, *35 U.S. Code § 103* obviousness rejections had the highest percentage at 30.37% [15].

An applicant can appeal the Examiner's final rejection to the Patent Trial and Appeal Board (PTAB). The PTAB is an administrative body comprised of the Director, the Deputy Director, the Commissioner for Patents, the Commissioner for Trademarks, and the administrative patent judges, who are people of competent legal knowledge. In the year 2020, 59.4% of ex parte appeals resulted in all rejections being affirmed [16].

In 2013, the *America Invents Act* created a system wherein the applicant who first files their application receives priority. Scholars of patents fear that the first-to-file regulation undermines fairness and equality in patent law. They argue that it is a disadvantage to inventors with fewer resources [17]. Furthermore, the first-to-file rule can encourage *35 U.S. Code § 103* obviousness rejections in that the declaration of surprising and unexpected results, i.e., MPEP §716.02 [18], are often unavailable during the expedited patent filing based on the timing [19], cost, and complexity of cancer research.

3 Conclusion

In the spirit of expanding drug development for cancer research, the USPTO should reconsider using 35 U.S. Code § 103 obviousness rejections for applications that teach novel therapies to inhibit cancer-related disease. Denials exclusively based on obviousness should not be a rate-limiting step for patentability and subsequent drug development for cancer research.

Compliance with ethical standards

Acknowledgments

The authors thank Cherie A. Benson and David L. Bartlett for their continued support.

Disclosure of conflict of interest

Michael J. Dochniak and Christopher J. Glancey are co-founders of Alleamit Corporation, Minnesota, USA.

References

[1] Cancer Treatment Centers of America. Busting Myths: Cancer is not just one disease [Internet]. COH Hold Co Inc. September 28, 2018. [cited 2022, Nov 17]. Available from https://www.cancercenter.com/community/blog/2018/09/busting-myths-cancer-is-not-just-one-disease

[2] National Center for Chronic Disease Prevention and Health Promotion. Cancer is the second leading cause of death in the United States [Internet]. CDC; [cited 2022, Nov 17]. Available from https://www.cdc.gov/chronicdisease/pdf/aag/divisionelevator_dcpc-508.pdf

[3] Prasad V, Mailankody S. Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval. JAMA Intern Med. 2017 Nov 1;177(11):1569-1575. doi: 10.1001/jamainternmed.2017.3601. Erratum in: JAMA Intern Med. 2017 Nov 1;177(11):1703. Erratum in: JAMA Intern Med. 2018 Oct 1;178(10):1433.

[4] United States Patent and Trademark Office. Meet the USPTO [Internet]. United State Department of Commerce; January 2016. [cited 2022, Nov 17]. Available from https://www.uspto.gov/sites/default/files/BasicFacts_1.pdf

[5] World Intellectual Property Organization. Frequently asked questions: Patent basics [Internet]. WIPO. [cited 2022, Nov 17]. Available from https://www.wipo.int/patents/en/faq_patents.html

[6] Gurgula O. Strategic Patenting by Pharmaceutical Companies - Should Competition Law Intervene? IIC Int Rev Ind Prop Copyr Law. 2020;51(9):1062-1085.

[7] Meyers DE, Meyers BS, Chisamore TM, Wright K, Gyawali B, Prasad V, Sullivan R, Booth CM. Trends in drug revenue among major pharmaceutical companies: A 2010-2019 cohort study. Cancer. 2022 Jan 15;128(2):311-316.

[8] Bar-Shalom A, Cook-Deegan R. Patents and innovation in cancer therapeutics: lessons from CellPro. Milbank Q. 2002;80(4):637-76, iii-iv.

[9] Shawnnay Holland. Inventions [Internet]. National Cancer Institute, Bethesda MD. Updated September 3, 2019. [cited 2022, Nov 17]. Available from https://techtransfer.cancer.gov/intellectualproperty/inventions

[10] Leavitt and Eldredge Law Firm. How much does a patent cost? What you need to know before starting! [Internet]. August 26, 2022. [cited 2022, Nov 17]. Available from https://uslawpros.com/how-much-does-a-patent-cost/#patent-types-have-their-cost-in-addition-to-the-patent-applications

[11] USPTO. Patents 4 Patients [Internet]. Last modified 2022, Oct 14. [cited 2022, Nov 17]. Available from https://www.uspto.gov/patents/initiatives/patent-application-initiatives/patents-4-patients

[12] Brundage K and Cosgrove J. Section 103 Rejections: How Common Are They and How Should You Respond? [Internet]. IPWatchdog. October 2, 2016. © 1999 – 2022 [cited 2022, Nov 17]. Available from https://ipwatchdog.com/2016/10/03/103-rejections-common-respond/id=73214/

[13] Wex definition team. Doctrine of Equivalence [Internet]. Legal Information Institute. Last updated in October of 2022. [cited 2022, Nov 17]. Available from https://www.law.cornell.edu/wex/doctrine_of_equivalents#:~:text=The%20doctrine%20of%20equivalents%20is,in%20the%20allegedly%20infringing%20product

[14] Patentbots. Art Unit 1699 [Internet]. Available from https://www.patentbots.com/stats/art-unit/1699

[15] Hellmann T. The Most Common Rejections: 102, 103, and 112(b) [Internet]. Juristat. © 2020 Datanalytics, Inc. [cited 2022, Nov 17]. Available from https://blog.juristat.com/most-common-rejections

[16] Szypa A. Patent Trial and Appeal Board Statistics Through January 2020 [Internet]. CarlsonGaskeyOlds. [cited 2022, Nov 17]. Available from https://cgolaw.com/patent-trial-and-appeal-board-statistics-through-january-2020/#:~:text=Institution%20rates%20for%20post%20grant,all%20concluded%20proceedings%20since%20FY13

[17] First-to File Rule for Patent Applications [Internet]. © 2022 Justia; Last reviewed October 2022. Available from https://www.justia.com/intellectual-property/patents/first-to-file-rule/

[18] USPTO. 716.02(a) Evidence Must Show Unexpected Results [Internet]. Last modified 06/25/2020. Available from https://www.uspto.gov/web/offices/pac/mpep/s716.html#d0e92844

[19] Adams, M. 5 things to know about the FDA approval process [Internet]. The University of Texas, MD Anderson Cancer Center; August 12, 2021. Available from https://www.mdanderson.org/cancerwise/5-things-to-know-about-the-fda-approval-process-.h00-159463212.html