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Radiotherapy and cancer treatment: IP challenges in Brazil

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Despite the availability of therapeutic options that extend life expectancy, cancer remains one of the leading causes of death worldwide. A key reason for this persistently high mortality rate is the limited effectiveness of conventional treatments in overcoming acquired tumor resistance.

Therefore, there is a long felt need for new treatment solutions that continues to drive pharmaceutical companies—particularly in the biotech sector—to invest massively in research and development (R&D).

One area where such investments have yielded significant results is radiotherapy (RT), a widely used and highly effective treatment for cancer with curative potential. Approximately half of all cancer patients receive and respond well to this therapy, which offers symptom and contributes to the preservation of quality of life.

RT works by causing irreversible DNA damage—including base damage, single- and double-strand breaks, and DNA interstrand crosslinks—to cancer cells. In the past decade, advancements in RT precision enabled the development of new techniques, such as proton RT, FLASH RT, and carbon ion (heavy ion) radiotherapy (CIRT). Recent studies show that those therapies have immunomodulatory effects, triggering a systemic antitumor response. An example is the abscopal effect: a systemic and long-distance effect that causes tumor regression at a nonirradiated metastatic site, driven by an immunogenic response.

Another promising approach is the use of radiopharmaceuticals. Unlike traditional RT, where radiation is administered from outside the body, radiopharmaceutical therapy delivers radiation directly to cancer cells, either by direct delivery or by means of delivery vehicles that are specifically targeted to the tumorous environment.

In recent years, immunotherapy (IMT) has profoundly transformed the treatment of several types of cancer. IMT is a method that enhances the activation of anti-tumor immune response and suppresses tumor development with fewer off-target effects. It encompasses the use of immune checkpoint inhibitors (ICI), adoptive cell therapy (ACT), vaccines, biologicals (cytokines, monoclonal antibodies, and antisera), and allogeneic hematopoietic stem cell transplantation (allo-HSCT). Despite being considered a breakthrough, especially for patients with advanced cancers, IMT presents an objective response rate that is low—around 10-30%—underscoring the need for combinatory treatment regimens to improve patient outcomes.

In light of these challenges, several studies have analyzed combining RT and IMT as a tool to

improve treatment. While some combinations demonstrate synergistic effects, the results are quite unpredictable, with the combination sometimes yielding positive, and other times negative, effects. This unpredictability suggests that combination therapies could be fertile ground for the development of pharmaceutical inventions aiming at combating forms of cancer with no effective treatment available.

However, securing patent protection for these innovations in Brazil presents significant challenges. Methods of treatment are considered non-statutory matter under Article 10(VIII) of the Brazilian IP Statute, and the acceptable format for claiming medical uses in Brazil is the Swiss-type claim, which pertains to the use of a compound for preparing a medicament. Therefore, treatments such as RT end up being considered as non patentable subject matter in Brazil.

The same applies to combination therapies involving medicaments and radiation. The BRPTO considers claims drafted based on the medicament with an indication that it is to be applied in combination with RT lack clarity and precision. According to the patent office, an instruction regarding the administration of the medicament (*e.g.*, in combination with another type of therapy) is inconsistent with the preparation of a medicament. This restrictive interpretation is harmful for a field where substantial resources are invested and where effective treatments are still needed for many types of cancers.

An alternative strategy for protecting these inventions is to use combination claims. Under the BRPTO's Examination Guidelines, combinations are considered products, which could make it easier to overcome clarity objections.

Another route is to use kit claims, specifying the combination with RT in the instructions for use. Given the restrictive landscape, it is interesting to diversify strategies, making room for creatively addressing eventual objections.

On a more optimistic note, the combination of chemotherapeutics with radiopharmaceuticals may offer a clearer path to patentability. Since radiopharmaceuticals are also formulations, it should be possible to protect these inventions using regular combination, use, and kit claims.

*Also co-authored by Tatiana Costa (RNA LAW)

Non-patent references

Sgouros, G., Bodei, L., McDevitt, M.R *et al.* Author Correction: Radiopharmaceutical therapy in cancer: clinical advances and challenges. *Nat Rev Drug Discov* **19**, 819 (2020). https://doi.org/10.1038/s41573-020-0085-5

Chandra, A., Drum, J., Daly, M. *et al.* Comprehensive measurement of biopharmaceutical R&D investment. *Nature Reviews Drug Discovery* **23**, 652-653 (2024) https://doi.org/10.1038/d41573-024-00131-2

Liu, S., Wang, W., Hu, S. *et al.* Radiotherapy remodels the tumor microenvironment for enhancing immunotherapeutic sensitivity. *Cell Death Dis*. 2023 Oct 13;**14**(10):679 (2023) doi: 10.1038/s41419-023-06211-2.

Zhang, Z., Liu, X., Chen, D. *et al*. Radiotherapy combined with immunotherapy: the dawn of cancer treatment. *Signal Transduct Target Ther*. 2022 Jul 29;7(1):258 (2022) doi:

10.1038/s41392-022-01102-y.

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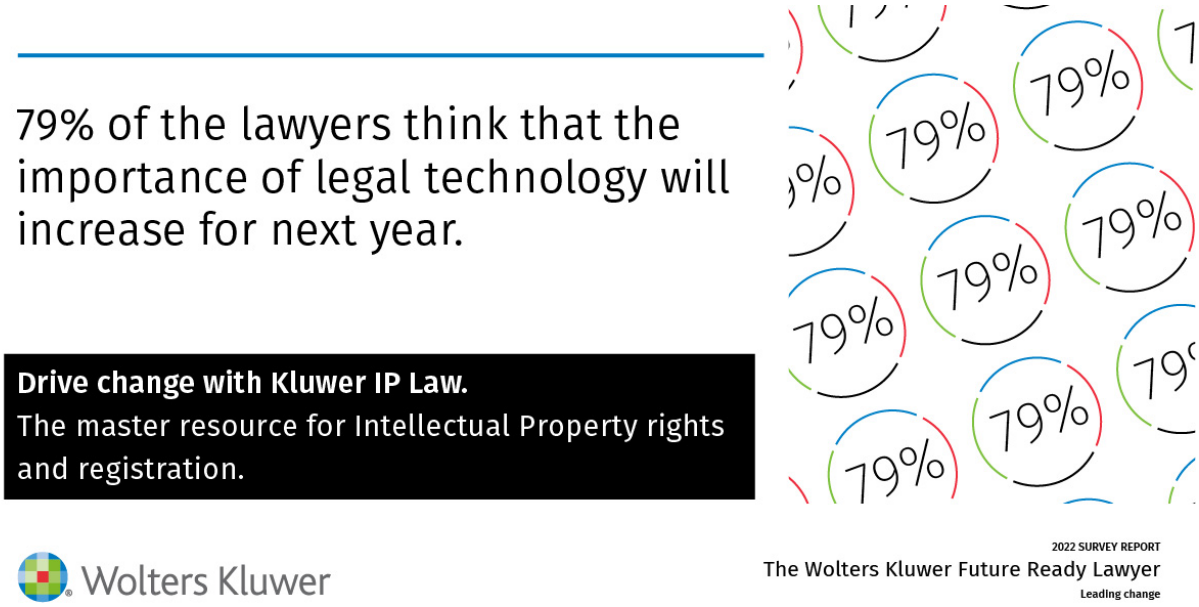

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