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IP CLIENT BRIEFING

A right royal(ty) mess: interpreting royalty obligations for second medical use patents

MAY 2024

/ INTRODUCTION

Drafting royalty provisions in patent licences can be a complicated process and care needs to be taken, particularly when the patents being licensed contain second medical use claims, to ensure that they reflect the parties' intentions.

A lack of clarity can lead to time-consuming and expensive disputes, and could result in the agreement being interpreted by a court in a way that one party may not have intended, as can be seen from the Court of Appeal's recent decision in **AstraZeneca UK Limited v Tesaro, Inc. [2024] EWCA Civ 78**.

In this briefing, we take a closer look at what that case was about, how the Court of Appeal interpreted the royalty provisions in question and what we can learn from it.

/ CONTENT

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WHAT WAS THE CASE ABOUT?

In a nutshell, the case was all about the correct interpretation of the royalty provisions in two patent sub-licences between AstraZeneca (as sub-licensor) and Tesaro (as sub-licensee).

Those sub-licences were granted pursuant to head-licences that AstraZeneca had previously agreed with each of the University of Sheffield and the Institute of Cancer Research.

The sub-licences were broadly on identical terms and granted Tesaro exclusive rights under certain licensed patents, which claimed second medical uses of, or methods of treatment using, existing compounds within the class of drugs known as PARP (poly ADP-ribose polymerase) inhibitors to treat specific types of cancer cells without needing to be used in conjunction with DNA-damaging treatments such as radiotherapy and chemotherapy. Instead, these PARP inhibitors could be used alone to target the homologous recombination (**"HR"**) pathway for DNA. Administering a PARP-inhibitor to an HR deficient (**"HRD"**) cancer cell would lead to breaks in the DNA which would remain unrepaired and therefore lead to the death of the cell.

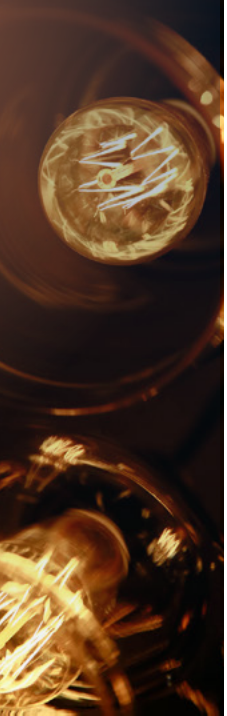
One such type of PARP-inhibitor is niraparib. Tesaro had intended niraparib to be used for treating patients who: (i) had specific gene mutations meaning they had a higher chance of being HRD, (ii) did not have those gene mutations, but were in any event deemed likely to be HRD, and (iii) had not been identified as being HRD. Not all of these expected uses fell within the scope of the licensed patents – Tesaro recognised that use (i) was likely to be in-scope, but uses (ii) and (iii) were less certain.

WHAT ARE SECOND MEDICAL USE PATENTS?

Second medical use patents are used to protect inventions relating to a new medical use of a known compound. For example, they may claim the use of a known drug to treat a new disease, or to treat a known disease using a new treatment regime (as was the case here). Second medical use patents do not, however, protect the compound or drug itself.

Putting this into context, in the present case, the licensed patents did not cover the PARP inhibitors themselves, but just the use of those inhibitors in particular treatment regimes.

In 2017, after obtaining relevant marketing authorisations, Tesaro began selling niraparib under the brand name, Zejula, as a treatment for certain types of cancer. Both parties recognised that some of the niraparib sales were for uses or treatments which fell outside the scope of the claims of the licensed patents, but a dispute arose as to the scope of Tesaro's royalty obligations. AstraZeneca claimed that Tesaro was obliged to pay royalties in respect of all sales of niraparib, regardless of whether those sales fell within the scope of the licensed patents. Tesaro, on the other hand, contended that royalties were only payable on sales of niraparib for uses claimed by the licensed patents, i.e. those uses which, in the absence of the licence, would infringe the claims of the licensed patents.



HOW WERE THE RELEVANT CLAUSES DRAFTED?

The key terms and definitions in the patent sub-licences that the Court of Appeal had to consider were drafted as follows:

- **Royalties clause:** "TESARO shall pay to AstraZeneca during the royalty term…a royalty of [X%] of the aggregate Net Sales of Licensed Products in the Territory…".
- **Royalty term:** "TESARO's obligation to pay royalties in respect of each Licensed Product shall commence, on a country-by-country basis, on the date of the First Commercial Sale of such Licensed Product in such country. In the event that in a particular country the First Commercial Sale of a Licensed Product occurs prior to the issuance in such country of a granted Patent which is a Licensed Patent that covers or claims the Exploitation of such Licensed Product, then royalties on such Licensed Product in such country shall be calculated…from the date of the First Commercial Sale of the Licensed Product and the accumulated aggregate amount of such royalties shall be paid by TESARO to AstraZeneca within thirty (30) days of the issuance in the relevant country of such Licensed Patent…TESARO's obligation to pay royalties shall expire, on a country-by-country basis, with respect to each separate Licensed Product, at such time as there is no longer any Valid Claim that covers or claims the Exploitation of such Licensed Product in such country".
- **Net Sales:** "the gross amount invoiced for Licensed Products by TESARO, its Affiliates and their sublicensees to Third Parties during such period, less allowances for the following deductions…"
- **Licensed Product:** "the Product and the Combination Products".
- **Product:** "any product in a form suitable for human applications that contains the Compound as the sole active ingredient".
- **Compound:** "TESARO's PARP inhibitor compounds niraparib and Mk-2512 *the use of which may be claimed or covered by…one or more of the Licensed Patents"* [emphasis added].

Reading these through, both the High Court and the Court of Appeal found that they all lead, one way or another, to the definition of "Compound" – with the key dispute between the parties relating to the meaning of the italicised words in that definition and, in particular, the meaning of the words "may be".

Tesaro submitted that the italicised words had the effect of limiting the scope of its payment obligation to sales of niraparib for uses or treatments falling within the scope of the licensed patents. It argued that those words simply indicate a point of time in the future, on the basis that certain of the licensed patents had not yet been granted at the date of the sub-licences and any commercialisation activity was some way off. AstraZeneca, however, disagreed and claimed that "may be" indicated some probability that the niraparib sold by Tesaro would be used in a manner that was covered by a claim of a licensed patent.

At first instance, the High Court found in favour of AstraZeneca and held that Tesaro had to pay royalties on all sales of niraparib in each country where at least one licensed patent subsists, regardless of whether those sales fell within the scope of the claims of the licensed patents.

THE COURT OF APPEAL'S DECISION

The Court of Appeal overturned the first instance decision, finding that royalties were only payable for sales of niraparib for uses covered or claimed by the licensed patents. Lord Justice Arnold, who gave the leading judgment, gave seven grounds for reaching this conclusion:

Meaning of "Compound"

1. Both the licence granted to Tesaro by AstraZeneca, and Tesaro's obligation to pay a royalty, use the term "Licensed Product" and, accordingly, depend on the definition of "Compound". In the context of scoping the licence, Lord Justice Arnold was satisfied that the italicised words used in the definition of "Compound" were intended to align the licence scope to the claims of the licensed patents. Accordingly, if given that meaning in the context of the licence scope, Lord Justice Arnold concluded that they must have the same function when used in the context of the royalty obligation.

2. The italicised words in the definition of "Compound" must be given some meaning and effect as they were obviously included for a purpose. As mentioned in ground 1 above, the apparent purpose was to align the scope of the royalty obligation with the scope of the patent claims and it is unclear "what other purpose they could be intended to serve".

3. The words "may be" in the definition of "Compound" should be interpreted as implying "futurity" rather than a probability for two reasons. Firstly, at the date of the agreements, some of the licensed patents had not been granted and it was uncertain whether they ever would be. Secondly, it was not clear at the date of the agreements whether Tesaro would ever receive regulatory authorisation to market niraparib. (However, not all of the judges agreed with this analysis. Whilst not determinative of his conclusion on the overall outcome, Lord Justice Birss's view was that the words "may be" referred to the existence of a possibility that the use could or might be claimed – as long as the possibility of that use being claimed wasn't wholly fanciful (e.g. use as a hair loss treatment), then it was covered. Such a construction would simplify the determination of the amount of royalty due, which Lord Justice Birss viewed as a non-trivial advantage.)

Royalty term

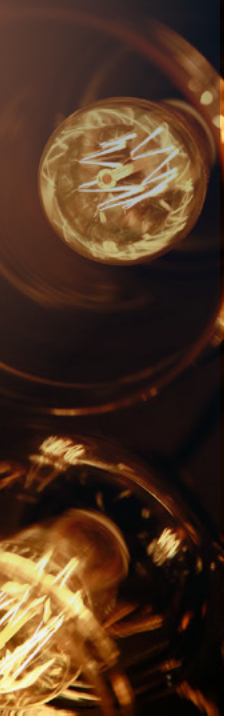
4. The royalty term covers the period for which there is a valid claim for the exploitation of the licensed product under a granted patent. This suggests that royalties were intended to be linked to the scope of licensed patent claims.

Lack of mechanism to determine which sales caught not unusual

5. It was not unusual that the licence agreements did not contain a mechanism to determine whether sales of niraparib were for uses or treatments that fell within the scope of the licensed patent claims. If that was expected to cause serious problems, the parties could have agreed a royalty obligation that was independent of the scope of the licensed patents, but they didn't do so.

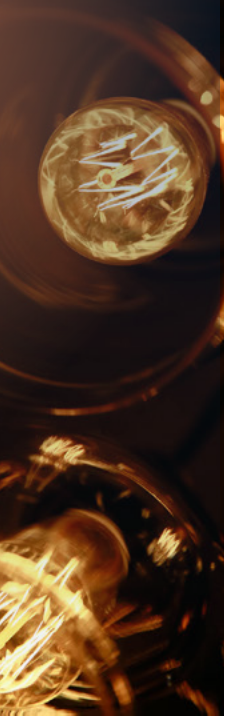
Illegality

6. Many of the patents licensed to Tesaro were US patents and the US was a major market for both parties. There was a serious risk that AstraZeneca's interpretation based on total sales of niraparib, rather than only those sales that fell within the scope of the licensed patents, could amount to "patent misuse" under US patent law and therefore be unlawful. When interpreting a clause with two possible meanings, one of which is lawful and the other unlawful, the former should be preferred. This was regarded by all three Court of Appeal judges as a particularly important factor that favoured Tesaro's interpretation.



Alignment with head-licences

7. Finally, the recitals to the sub-licences that had been granted by AstraZeneca to Tesaro cross-referred to AstraZeneca's head-licences (which Tesaro had seen before signing the sub-licences). Those head-licences, in turn, required AstraZeneca to pay royalties to the head-licensors only on sales covered by the licensed patents (with no contractual mechanism for determining when sales were for uses falling within the scope of those patents). Tesaro argued that this supported its interpretation and the Court of Appeal agreed. Whilst the wording in the two sets of agreements was slightly different, the Court of Appeal found that a reasonable reader would conclude that they intended to express the same idea. This was supported by evidence of an email sent by AstraZeneca to Tesaro during the negotiations for the sub-licence agreements which indicated that the downstream royalties (from Tesaro to AstraZeneca) matched the upstream royalties (from AstraZeneca to the head-licensors), which would only be the case if the head- and sub- licences had royalty obligations of the same scope.



COMMENT AND PRACTICAL TAKEAWAYS

This is an interesting decision that highlights some of the potential pitfalls and challenges when drafting royalty provisions in second medical use patent licences. Whilst cases like this will always ultimately depend on their specific facts, there are several broader points we can take away:

- **Clear and consistent drafting is key:** as with all complex commercial agreements, clear and consistent drafting is key to avoiding unforeseen consequences. This is particularly important for royalty clauses and other payment obligations in IP licences which, if poorly drafted, can significantly alter the intended commercial deal.

- **Scope of licence and royalty obligation may be different:** don't assume that the scope of the royalty obligation will be treated as aligned with the scope of the licensed patents. What matters is the wording of the royalty obligation itself. In some circumstances, it may be appropriate for parties to a patent licence to agree a royalty obligation which extends beyond the scope of the licensed patents.

- **Extra care is required where second medical use patents are being licensed:** while conceptually it may seem logical to agree that royalties will be calculated based on sales that would infringe the claims of the licensed patents absent the licence agreement, it may be hard in practice to determine when infringement of a second medical use claim occurs. Consideration should be given to whether a commercial model that calculates royalties by reference to more easily determined criteria (e.g., all sales, all sales for use as a treatment for a particular disease or all sales for indications covered by a relevant marketing authorisation) may be more appropriate (subject to the next bullet point below). Whatever is agreed commercially, the parties should be clear on how any royalties will be calculated in practice and make sure that the drafting clearly reflects that approach.

- **Drafting of head-licences could influence interpretation of sub-licences:** if a sub-licence cross-refers to a head-licence under which it was granted, the English courts may look to the drafting and intention behind provisions in the head-licence when seeking to interpret ambiguous provisions in the sub-licence. This should be borne in mind when considering how to draft a sub-licence to achieve the parties' commercial intention.

- **Consider whether to get local law advice:** this case highlights the impact that foreign law can have on the interpretation of an English law governed agreement. Given the English courts' clear preference for a lawful interpretation of an ambiguous clause over an unlawful one, parties should carefully consider whether to seek local law advice when drafting patent licences covering countries other than the UK. The US "patent misuse" doctrine was relevant in this case given US patents were being licensed and the US was a major market for both parties. And so this is certainly something for those operating in the US to be mindful of. However, this principle appears to be one of broader application and could therefore arise with respect to other jurisdictions or in different contexts. As a result, depending on the profile of the patent portfolio being licensed, it may be prudent to seek a local law review by local counsel in material jurisdictions outside the UK, particularly where total sales royalties are being considered.