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PERSPECTIVES

CHALLENGES IN DAMAGES QUANTIFICATION INVOLVING EARLY-STAGE INTELLECTUAL PROPERTY

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The valuation of intellectual property is frequently a significant issue in the damages phase of disputes between companies in innovative industries. The selection of appropriate valuation methods, and the application of those methods to the specific facts of the dispute, present challenges to the damages expert and to the finder of fact (whether this is a judge, jury or arbitral tribunal). These challenges may be especially acute in disputes involving intellectual property assets that have not been incorporated in a commercialised product as of the date of the conduct at issue (for convenience, we refer to this as 'early-stage intellectual property'). In this article, we review some of the sources of these difficulties and methods that

may be considered to value early-stage intellectual property.

Early-stage valuation issues can arise in damages quantification in a variety of contexts. For example, a company conducting research and development toward the possible introduction of a future product may allege that a rival has misappropriated confidential information that could enable it to introduce a competing product in the future. The owner of the confidential information may seek compensation for the diminution in the value of its prospective business opportunity, or disgorgement of the prospective gain experienced by the rival. Alternatively, a party to a collaborative product development agreement may allege that its

counterparty breached the contract by shirking its development obligations, resulting in a decreased prospect of technological or marketplace success.

Several conventional asset valuation methods exist, which may have some relevance to intellectual property in general. First, the cost-based approach seeks to value an asset by measuring the cost of replacing it via the development of an asset with sufficiently similar functionality. In the intellectual property context, this can be thought of as the cost of 'designing around' the intellectual property at issue. However, many forms of intellectual property derive value principally from benefits realised in the marketplace that are specific to the asset, and such benefits may bear little relationship to the cost of producing (or reproducing) the asset itself. Accordingly, valuation approaches based on replacement cost tend to have applications limited to situations where value is not primarily driven by demand in the marketplace but instead may derive from improvements or efficiencies in processes that are otherwise reasonably well understood.

Second, the market-based or transactional approach seeks to value an asset by observing the price paid for the asset (or comparable assets) in actual market transactions between unrelated parties. Such approaches are commonly used in the intellectual property context and have the advantage of directly measuring the benefits deemed by market participants to be inherent in access to the intellectual property. In situations in which prior





transactions exist for the intellectual property to be valued in the dispute, information on the prices paid by sellers may be accorded a high degree of weight. Note that a 'price' for access to the intellectual property may take the form of a royalty on sales, a lump-sum acquisition price, an equity investment in the seller, a combination of fees over time that may include milestone payments, and any number of other structures. If no transactions have occurred for the specific intellectual property at issue, it may still be possible to find examples of market transactions involving assets that are sufficiently comparable to be informative for valuation purposes. Prior comparable transactions may or may not include the parties to the dispute. Judgment and care are required to ensure assessments are based on sufficiently comparable circumstances or appropriate compensating adjustments are made for differences; if the sample contains bad data, then inferences based on the sample will tend to be unreliable.

Third, the income-based approach may be used to derive an estimate of value based on direct modelling of the future cash flows expected to be realised from access to the asset and the discounting of those cash flows back to a relevant point in time. This method is often applied in situations where reliable market-based estimates of value cannot be obtained. Valuation by means of such a discounted cash flow approach can be highly informative, but it also requires a significant

investment in determining the appropriate inputs to the modelling process. These inputs include estimates of the revenues and costs associated with deployment of the intellectual property; the probability and timing of those realisations; the duration of the time period over which the assessment is to be conducted; and the rate by which the resulting expected cash flows should be discounted back to the present to arrive at an estimate of the net present value of access to the intellectual property. The output of the modelling process tends to be highly dependent on assumptions made about these various inputs. Nonetheless, it is a virtue of this method that it allows for the sensitivity of the resulting valuation estimate to be tested against variations in any input to the model.

Whatever the strengths and weaknesses of these methods in general, there are specific challenges in using them to value early-stage intellectual property. Disputes involving early-stage valuation are especially common in the pharmaceutical industry. This is to be expected given the industry's long research and development timelines, rich intellectual property environment, potentially lucrative product opportunities, and frequency of collaborative arrangements for development and commercialisation. Accordingly, it is useful to focus

on a concrete, stylised example that highlights some of the difficulties that may be encountered.

Consider a company, A, that owns the rights to a new drug product candidate, X, that is on the cusp of entering the first phase of human clinical trials

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for treatment of certain forms of cancer. Drug X is the result of a lengthy process of drug discovery, including the screening of potential compounds alone and with other known compounds as well as a range of other costly and time-consuming tests; this confidential information comprises the intellectual property at issue. It is known that drugs at X's stage of development face a high risk of failure in clinical trials but, given the disease area, the market opportunity in the event of success is large. Company A alleges that its rival, company B, misappropriated A's confidential information, invigorating B's drug discovery programme and

leading to another product candidate, Y, that would compete with X if successfully approved. Assuming the alleged misappropriation is proved, how can A's intellectual property be valued in such a way that results in appropriate compensation?

First, note that the cost of the discovery work leading to drug X is unlikely to be commensurate with its potential value; if it were simply a matter of putting in laboratory time and resources, promising cancer drug candidates would be thick on the ground, yet they are scarce. Second, due to the nature of the intellectual property, no prior transactions would be expected to exist; there is no observed market price for access to the confidential information. Third, an income-based approach to valuation may be problematic: the launch of drug X, if approved, may be several years in the future, and it may be difficult to generate reliable estimates of revenues and costs for a market environment that may change materially before the product even appears on the market. Courts or arbitrators may deem the likelihood of approval, and therefore the prospect of any realised value for the intellectual property underlying drug X, to be too remote and therefore the valuation too speculative. Moreover, since the fundamental question in this hypothetical case is the change in the value of X due to the alleged misappropriation, and this *change* only occurs in the (potentially) unlikely event that both X and Y succeed, any prospect of compensation seems even further removed.

A creative approach that combines different methods may be needed to break the impasse. For example, suppose there is an active market for acquisitions of early-stage cancer drug candidates targeted at the same or similar cancer types as drug X, and the prices for these acquisitions can be observed from public sources. This is a type of market evidence that may be informative, even if it does not directly represent the value of the information underlying drug X; at a minimum, it indicates that the market price for early-stage drug candidates may be significant, and therefore information facilitating discovery of such candidates is of value. Suppose also that company B has performed its own internal market opportunity studies on the potential profitability of drug Y, and that it can be documented on technical grounds that the alleged misappropriation resulted in an earlier discovery of drug Y, and therefore earlier potential launch, than would have occurred without the alleged misappropriation. In that case, a hybrid cost-based and income approach may be derived to measure the amount company B would be willing to pay in order to avoid this delay in discovery and potential launch.

Finally, other novel approaches to valuation that combine elements of the three basic methods may be worth considering. Changes in the company valuation may provide insight into the value of early-stage intellectual property. Continuing the example, if company B were privately held, an

influx of investment capital following the alleged misappropriation may provide a market-based valuation of the assets. Alternatively, contingent valuation simulation models can vary the probability of favourable product development and the payoffs associated with that outcome to provide expected values. While modelling techniques and iterative procedures allow statistical robustness, whether courts or arbitrators find this approach compelling will likely depend on several factors, including how well the assumptions tie to the information available in the dispute. Market research provides a less mechanistic approach, involving market participants and potential industry experts to rank or evaluate the likely commercial viability of different early-stage intellectual property. The applicability of such an approach may depend on whether the research was conducted before the dispute, the objectivity of the information provided to solicit responses, and whether courts or arbitrators find an amalgamation of expert opinion to be compelling.

While there are challenges associated with valuation of early-stage intellectual property, proper consideration acknowledges that misappropriation of assets can cause harm, even if that intellectual property is not yet embodied by a commercialised product. A careful application of established and innovative approaches can assist in the resolution of disputes, perhaps even before those products become available. **CD**

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