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The Doctrine of Equivalents in Balancing Patent Exclusivity and Generic Competition: Insights from the Novartis v. Pharmathen Dutch Jurisprudence

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Abstract
The intersection of pharmaceutical patent protection and public health imperatives presents a persistent global challenge, particularly in reconciling innovation incentives with affordable access to medicines. This legal memorandum examines the application of the doctrine of equivalence in Novartis v. Pharmathen before the Dutch courts and analyzes its relevance for the development of Indonesian patent law under Law No. 13 of 2016 concerning Patents. The central issue is whether a pharmaceutical process that does not literally fall within a patent claim may nevertheless constitute infringement when it performs substantially the same function and achieves substantially the same technical result as the claimed invention. This research employed a normative juridical method, utilizing statutory, case, comparative, and conceptual approaches to examine relevant legislation, judicial decisions, and legal doctrine. The analysis focuses on the Dutch courts' decisions, which applied principles developed in Eli Lilly v. Actavis, concluding that Pharmathen's generic production process infringed Novartis' patent through equivalence, despite formal differences in manufacturing steps. The courts emphasized that patent protection must carefully balance fair protection for patent holders against legal certainty for third parties, including generic producers and the public. This memorandum concludes that while the doctrine of equivalence can prevent the avoidance of patent liability through minor modifications, its application requires robust safeguards against excessive patent expansion and evergreening practices. The case offers instructive lessons for Indonesia in developing a balanced patent framework that protects pharmaceutical innovation while maintaining fair competition and public access to medicines, an area where Indonesian jurisprudence remains comparatively underdeveloped.

INTRODUCTION

The pharmaceutical industry constitutes one of the most innovation-driven and research-intensive sectors in the modern global economy, with research and development expenditures consistently surpassing those of other high-technology industries (Gawel, 2016; Grabowski et al., 2015). The development of pharmaceutical products requires extensive scientific experimentation, clinical trials, regulatory compliance, and substantial financial investment, with estimates suggesting that the average cost of bringing a new drug to market exceeds USD 2.6 billion (DiMasi et al., 2016). As a result of the increased time needed for testing and other regulatory requirements, the effective period of market protection available to recoup investment can be substantially reduced, thus heightening the perceived importance of exclusivity mechanisms such as patents and regulatory data protection (Grabowski et al., 2015; Hutt, 1982). The high risks associated with pharmaceutical research and development

have made patent protection an essential legal mechanism for safeguarding innovation and providing economic incentives for inventors and pharmaceutical corporations, with studies confirming that patents are particularly critical in the pharmaceutical sector compared to other industries (Greenbaum, 2012; Grabowski, 2002).

Patent law grants exclusive rights to inventors for a limited period, typically twenty years from the filing date, allowing them to prevent unauthorized production, use, or commercialization of patented inventions (Dinh, 2004). In the pharmaceutical sector, patents play a particularly strategic role because they help innovator companies appropriate returns on innovation and mitigate free-riding incentives that would otherwise allow imitators to leverage the innovator's regulatory approval and development costs without bearing the associated risks and expenses (Grabowski, 2002; Grabowski, 2003). Consequently, patents and regulatory exclusivity provisions are often treated as core tools for sustaining biopharmaceutical R&D incentives, even as policy debate continues about how to balance innovation incentives with generic utilization and price competition (Grabowski et al., 2015). Data from the pharmaceutical industry indicate that patent protection is responsible for approximately 80% of the revenues generated by new molecular entities, underscoring the economic significance of robust patent enforcement for innovator firms (Grabowski et al., 2015).

However, strong patent protection frequently creates tension with the need to preserve market competition and ensure public access to affordable medicines, particularly in developing countries where healthcare budgets are constrained and out-of-pocket expenditures remain high ('t Hoen, 2002; Grabowski et al., 2015). Prohibitive drug prices are often linked to strong intellectual property protection, and the TRIPS Agreement has been criticized, particularly by developing countries and non-governmental organizations, for potentially constraining public-health policy space in ways that affect access to essential medicines ('t Hoen, 2002; Van Eeckhaute, 2002). Empirical evidence suggests that generic competition can reduce drug prices by 80-90% compared to branded products, making the timely entry of generic medicines a critical factor in improving healthcare affordability and access (Shanmugaiah, 2012; World Health Organization, 2018). At the same time, access to affordable medicines in developing countries is closely connected to generic competition and access to cheaper medicines of assured quality, with TRIPS-recognized tools such as compulsory licensing, parallel importation, and bolar provisions seen as mechanisms to increase access to generic drugs while maintaining compliance with international obligations (Shanmugaiah, 2012; 't Hoen, 2002).

The tension between pharmaceutical innovation and generic competition has become increasingly complex in modern patent litigation, particularly regarding the interpretation of patent claims and the extent to which protection is limited to literal claim language versus extended to cover equivalents (Holman, 2020; Wang et al., 2011). In response to this challenge, many jurisdictions have developed or revived doctrines of equivalence to prevent the avoidance of patent liability through insubstantial variants that appropriate the benefits of the patented invention without literal infringement, while also seeking to preserve legal certainty for third parties through limiting principles such as prosecution-history estoppel and the public dedication doctrine (Holman, 2020; Wang et al., 2011). The doctrine of equivalence is a patent law principle that allows courts to find infringement even when the accused product or process does not literally fall within the wording of the patent claims, provided that the accused element

is treated as equivalent to a claimed element under the jurisdiction's test for equivalence (Holman, 2020). This doctrine has been described as a necessary corrective to the inherent limitations of language in capturing the full scope of an inventor's contribution, ensuring that patentees receive fair protection against copyists who make only trivial changes to avoid literal infringement (Johnson, 2017; Jadeja et al., 2018).

In the United States, the function-way-result approach is a commonly referenced articulation for assessing equivalence, requiring that the accused element performs substantially the same function, in substantially the same way, to achieve substantially the same result as the claimed element (Holman, 2020). Comparative accounts note that European approaches adopt conceptually similar reasoning under different doctrinal labels and traditions, with the European Patent Convention's Protocol on the Interpretation of Article 69 providing the foundational framework for claim construction and equivalence analysis across member states (Takenaka, 2006; Cohen, 1998). However, comparative scholarship emphasizes that even when jurisdictions use similar interpretive methodologies, the practical "extent of patent protection" can diverge significantly, and one driver of divergence is the availability and calibration of the doctrine of equivalents (Takenaka, 2006). Within the European patent system, claim interpretation has historically sought a compromise between a more literal, claims-as-"fence posts" tradition and a more purposive, "central teaching" tradition, which has been described as a "via media" that balances fair protection for patentees with legal certainty for third parties (Cohen, 1998). This interpretive backdrop is important because it frames how European legal systems can justify protection that is not confined to literal wording, while still aiming to preserve legal certainty for third parties through structured approaches to claim construction and limits on the use of prosecution materials (Johnson, 2017; Cohen, 1998).

A major turning point in European patent jurisprudence occurred in the case of *Eli Lilly v Actavis* [2017] UKSC 48, where the United Kingdom Supreme Court held that a patent can be infringed by "immaterial variants" and reformulated the *Improver* questions, a decision viewed as having far-reaching ramifications for infringement assessment in the UK and across Europe (Jadeja et al., 2018; Johnson, 2017). The *Actavis* decision established a structured framework for assessing equivalence, requiring courts to consider whether the variant achieves substantially the same result in substantially the same way, whether it would have been obvious to the skilled person that it would achieve that result, and whether the variant is a material departure from the inventive concept (Jadeja et al., 2018). Commentary further characterizes the decision as an attempt to strike a balance between rewarding patentees, including protection against an "unscrupulous copyist," and the public interest in promoting competition and preventing the extension of patent monopolies beyond their legitimate scope (Jadeja et al., 2018; John, 2019). Yet the post-Actavis landscape also raises a recurrent caution: if the "inventive concept" is defined too broadly, the effective scope of protection under equivalents can become correspondingly broad, potentially reducing certainty for competitors and encouraging evergreening strategies that extend exclusivity beyond the legitimate patent term (John, 2019; Abbas, 2019).

High-stakes pharmaceutical patent enforcement can therefore be understood as a site where innovation incentives and competitive entry pressures meet, and where doctrinal choices about claim scope can meaningfully shift bargaining power between originator and generic firms (Drexl & Lee, 2013; Grabowski et al., 2015). In the EU context specifically, policy and

academic literature notes that firms facing patent expiry may employ lifecycle-management strategies that can include potentially abusive "ever-greening" practices, such as filing secondary patents on formulation, dosing, or manufacturing methods, or seeking regulatory extensions, with significant consequences for the timing and magnitude of generic competition (Drexl & Lee, 2013; Abbas, 2019). Empirical research has shown that evergreening can delay generic entry by several years, imposing substantial costs on healthcare systems and patients, and has prompted policy responses including patent opposition mechanisms and enhanced patent examination standards (Mallo et al., 2008; Faunce & Lexchin, 2007). The *Novartis v. Pharmathen* dispute reflects this broader policy conflict within pharmaceutical patent law, in which infringement analysis can determine whether follow-on competitors are excluded even when they implement non-literal variants of a patented teaching, raising fundamental questions about the proper scope of patent protection and the balance between innovation incentives and public access (Holman, 2020; Drexl & Lee, 2013).

From the perspective of innovator companies, strong patent protection is necessary to maintain incentives for expensive pharmaceutical research and development, and patents have been found to be particularly important in pharmaceuticals for appropriating the benefits from innovation compared with other high-tech industries (Grabowski, 2002; Greenbaum, 2012). This logic is reinforced by the free-riding concern that, absent patent protection, imitators could leverage the innovator's regulatory approval and duplicate products at a small fraction of the originator's cost, thereby undermining the economic rationale for investment in new drug development (Grabowski, 2003). Conversely, excessive patent protection may restrict market competition and delay the entry of affordable generic medicines, raising concerns about access and cost containment, particularly in developing countries with limited healthcare resources ('t Hoen, 2002; Grabowski et al., 2015). Evergreening is frequently framed as a serious challenge for access to affordable drugs because it can delay generic competition by extending exclusivity beyond the legitimate patent term without commensurate therapeutic improvement, and follow-on patenting can keep generic competitors off the market and make immediate review mechanisms important to prevent ultimately invalid patents from hindering entry (Abbas, 2019; Mallo et al., 2008). Comparative discussions of linkage-style regulatory arrangements further suggest that features of the pharmaceutical regulatory system can amplify these effects by delaying generic approvals and thereby affecting drug costs and access to essential medicines (Faunce & Lexchin, 2007).

The controversy surrounding claim scope and equivalence becomes particularly relevant for developing countries such as Indonesia, where public-health policy and affordability concerns shape the social stakes of patent enforcement and the availability of generic medicines ('t Hoen, 2002; Van Eeckhaute, 2002). Indonesia's patent law, Law No. 13 of 2016 concerning Patents, includes safeguards recognized under TRIPS, such as parallel importation, bolar provisions, compulsory licenses, and government use, which are relevant tools for maintaining policy space when exclusivity threatens access to medicines (Maulana & Abadi, 2025). However, Indonesian scholarship emphasizes the recurring tension between patent protection and the public's need for access to affordable medicines, with compulsory licensing often proposed as a balancing mechanism consistent with TRIPS flexibilities, including TRIPS Article 31 and the Doha Declaration on the TRIPS Agreement and Public Health (Maulana & Abadi, 2025). Indonesia has also issued implementing regulation on

compulsory patent licensing procedures (Permenkumham No. 30 Tahun 2019), illustrating that the legal architecture already contains formal tools intended to mitigate exclusionary effects where appropriate (Dandy Hediyanto et al., 2021). In Indonesia's national health insurance context, the use of medicines in JKN refers to Formularium Nasional (Fornas), and BPJS has relied on interim price and product guidance while the e-catalog is developed, making procurement and formulary design central to affordability and access outcomes (Anggriani et al., 2020; Yuniarti et al., 2019).

Previous research on the doctrine of equivalence in the Indonesian context remains limited, with most scholarly attention focused on general patent law principles or specific topics such as compulsory licensing and traditional knowledge protection (Maulana & Abadi, 2025; Dandy Hediyanto et al., 2021). Studies from other jurisdictions have examined the application of equivalence doctrine in pharmaceutical patent disputes, but comparative analyses specifically addressing the implications of European jurisprudence for Indonesian patent law development are scarce (Holman, 2020; Takenaka, 2006). This research gap is significant because Indonesia, as a middle-income country with a growing pharmaceutical industry and expanding universal health coverage, faces the challenge of developing a patent framework that simultaneously protects innovation and ensures access to affordable medicines. The *Novartis v. Pharmathen* case therefore provides a useful point of departure for Indonesian patent law development because it invites a structured inquiry into how an equivalence-based infringement analysis might affect both innovation incentives and generic entry, and how any expansion of non-literal enforcement should be paired with safeguards against over-extension and evergreening risks (Abbas, 2019; Grabowski et al., 2015).

The urgency of this research is underscored by several factors. First, Indonesia's pharmaceutical market is projected to grow significantly in the coming years, driven by population growth, rising incomes, and the expansion of national health insurance coverage, making patent policy increasingly consequential for public health outcomes. Second, the ongoing negotiation of trade agreements and the evolving interpretation of TRIPS flexibilities require Indonesia to develop a clear and balanced approach to pharmaceutical patent enforcement. Third, the experience of other middle-income countries suggests that the absence of a clear equivalence framework can lead to either excessive patent protection that delays generic entry or insufficient protection that undermines innovation incentives. Fourth, the *Novartis v. Pharmathen* decision represents a significant development in European patent jurisprudence that may influence judicial practice in other jurisdictions, including through the global dissemination of legal reasoning. Comparative experience suggests that doctrinal design choices can shift the practical extent of patent protection across jurisdictions, including through the availability of equivalence doctrines, making careful calibration essential if Indonesia were to develop a more explicit equivalence framework (Takenaka, 2006).

The novelty of this research lies in its specific focus on the *Novartis v. Pharmathen* case as a lens for analyzing the implications of equivalence doctrine for Indonesian patent law, a perspective that has not been systematically explored in the existing Indonesian legal literature. This research contributes to the scholarship by providing a detailed doctrinal analysis of the Dutch courts' application of equivalence principles, drawing comparative lessons for Indonesia's patent system, and offering practical recommendations for the development of Indonesian patent law that balances innovation incentives with public health imperatives. The

research further evaluates whether adopting broader equivalence principles within Indonesian pharmaceutical patent enforcement would appropriately balance the protection of pharmaceutical innovation with the preservation of fair generic competition and public access to affordable medicines (Shanmugaiah, 2012). Accordingly, this research examines the application of the doctrine of equivalence in a European pharmaceutical litigation context and analyzes its implications for Indonesian patent law, with attention to public-health safeguards and market-access effects (Grabowski et al., 2015).

The purpose of this research is to analyze the application of the doctrine of equivalence in *Novartis v. Pharmathen* and to derive lessons for the development of Indonesian patent law under Undang-Undang Nomor 13 Tahun 2016 tentang Paten, particularly in balancing innovation incentives with access to affordable medicines. The research objectives are twofold: first, to examine how the Dutch courts applied the doctrine of equivalence in *Novartis v. Pharmathen* and how that application reflects the tension between pharmaceutical patent protection and generic competition; and second, to identify lessons from the *Novartis v. Pharmathen* case for the future development of Indonesian patent law, including the safeguards necessary to prevent excessive patent expansion and evergreening practices. The research benefits are threefold: theoretically, it contributes to the comparative patent law literature by analyzing the application of equivalence doctrine in a significant European pharmaceutical case; practically, it provides guidance for Indonesian policymakers, judges, and legal practitioners on the potential implications of equivalence-based infringement analysis; and socially, it aims to inform the development of a balanced patent framework that protects pharmaceutical innovation while safeguarding public access to essential medicines.

METHOD

This research employed a normative juridical or doctrinal legal research methodology to analyze the legal principles governing patent infringement and the doctrine of equivalence. This approach is consistent with established legal scholarship that examines how courts interpret and apply legal rules to concrete disputes, with the aim of extracting doctrinal coherence and normative implications for policy development (Marzuki, 2017; Soekanto & Mamudji, 2015). The research population consists of all primary and secondary legal materials relevant to the doctrine of equivalence in pharmaceutical patent disputes, including judicial decisions, statutes, treaties, and scholarly commentary. The data sample is purposively selected to include the key judicial decisions from the Dutch proceedings in *Novartis v. Pharmathen*, specifically the preliminary injunction decision from the District Court of The Hague on 19 July 2022 (Case number C/09/625801 / KG ZA 22-201) and the subsequent ruling from the Court of Appeal of The Hague on 15 November 2022 (Case no. ECLI:NL:GHDHA:2022:2327), as well as the Supreme Court decision denying cassation on 17 May 2024. The sampling technique employed is purposive sampling, which involves the deliberate selection of legal materials that are most relevant and informative for addressing the research problems, ensuring that the analysis is focused on the most authoritative and precedent-setting sources (Creswell & Poth, 2018; Denzin & Lincoln, 2018).

The research instrument used in this doctrinal study is a document analysis checklist, which serves as a structured guide for extracting and categorizing information from the selected legal materials. This checklist includes key variables such as the legal issues presented, the

applicable legal rules, the court's reasoning, the application of the doctrine of equivalence, and the implications for patent enforcement and generic competition. Validity in doctrinal legal research is established through the use of authoritative primary sources and the triangulation of findings across multiple sources, including judicial decisions, statutory provisions, and scholarly commentary (Hutchinson, 2015; Dobinson & Johns, 2017). Reliability is ensured through systematic and transparent documentation of the research process, including clear articulation of the analytical framework and the use of consistent criteria for selecting and interpreting legal materials (Van Hoecke, 2011; Chynoweth, 2008). The data collection technique employed is document study, which involves the systematic collection, review, and analysis of primary and secondary legal materials relevant to the research questions (Doctrinal legal research, 2020). The procedure for data collection follows several stages: first, identification and collection of relevant primary legal materials, including the Dutch judicial decisions and the applicable provisions of the European Patent Convention and Indonesian Patent Law; second, identification and collection of secondary legal materials, including academic articles, expert commentaries, and comparative legal analyses from databases such as Google Scholar and Scopus; third, systematic review and extraction of relevant information from the collected materials using the document analysis checklist; and fourth, organization and categorization of the extracted information for subsequent analysis.

Data analysis is conducted using qualitative methods, including interpretation and systematic reasoning, which are characteristic of doctrinal legal research (Hutchinson, 2015; Dobinson & Johns, 2017). The analytical framework employed in this study consists of three interrelated approaches. First, the statute approach examines relevant legal frameworks, including Indonesia's Law No. 13 of 2016 concerning Patents (UU 13/2016), Article 69 of the European Patent Convention (EPC), and its accompanying Protocol on the Interpretation of Article 69, to establish the applicable legal rules governing patent scope and equivalence. Second, the case approach focuses on the precedent-setting European decisions in *Eli Lilly v. Actavis* and the specific application of those principles in the Dutch *Novartis v. Pharmathen* case, analyzing how courts have interpreted and applied equivalence doctrine in practice. Third, the comparative approach contrasts the doctrinal developments in Dutch and European patent law with the current legal landscape in Indonesia, identifying similarities, differences, and potential lessons for Indonesian patent law development. A conceptual approach is also applied to explore the underlying tensions between innovation incentives, generic competition, and public access to medicines, drawing on theoretical frameworks from patent law, competition policy, and public health scholarship (Drexl & Lee, 2013; Grabowski et al., 2015). The analysis is facilitated by the use of reference management software (e.g., Mendeley) for organizing citations and legal sources, and word processing software for document preparation and analysis. The analysis is prescriptive in nature, aiming to derive actionable lessons and provide recommendations for the future development of Indonesian patent law, particularly in balancing the competing interests of pharmaceutical innovators and the public. The findings are presented in a structured narrative that integrates doctrinal analysis, comparative insights, and policy recommendations, with the goal of contributing to both academic scholarship and practical legal development in Indonesia.

RESULT AND DISCUSSION

European Doctrinal Structure

The *Novartis v. Pharmathen* case illustrates how European courts frequently operationalize equivalence through structured "requirement" or "question" sets rather than through an impressionistic fairness assessment. The Dutch Court of Appeal expressly anchored its approach in a prior *Pemetrexed*-related framework, signalling a deliberate choice to treat equivalence as governed by a repeatable test rather than as an ad hoc extension of claim scope .A useful way to show convergence and divergence in the source set is to place the Dutch and German/UPC-style frameworks side by side, focusing on what each makes central: (i) problem/function performance, (ii) the skilled person, and (iii) limiting principles designed to constrain overreach beyond what can legitimately be claimed and protected (Pinsent Masons, 2026).

Table 1. The table below summarises the structured tests explicitly described in the provided sources.

Jurisdictional frame (as described in sources)	Structure of equivalence analysis	Explicit limiting idea described in sources
Netherlands (Hague Court of Appeal)	"Four requirements for equivalence" from Eli Lilly v. Fresenius / Pemetrexed; accused method "solves the problems underlying the patent" and substitute "fulfils the same function" as claimed element	"Equitable protection of the patent holder" and "a sufficient degree of legal certainty" assessed through the skilled person's understanding that "claims leave room for equivalents"
Germany (BGH line as summarised)	Structured inquiry described through three questions emphasising objectively equivalent means, skilled person recognition of same effect, and claim-anchored focus on "essential meaning"	Fromstein rule: "no infringement by equivalence if the accused embodiment is not eligible for patent protection"; Fromstein defence precludes extension to embodiments that are not novel or are obvious over prior art
UPC-oriented commentary	"Infringement analysis … required that three questions be addressed," including problem solved with "objectively equivalent means" and whether the skilled person can identify the same effect, with the skilled person's considerations focused on the claim's "essential meaning"	The source frames the analysis as claim-anchored via "essential meaning" of the claim teaching, indicating a constraint internal to the test rather than an external defence in the excerpted description

Within this comparative frame, the Dutch Court of Appeal's explicit attention to both "equitable protection" and "legal certainty" is significant because those terms make the balancing structure of equivalence visible on the face of the doctrine rather than being treated as mere background policy. The Court of Appeal's explanation of legal certainty i.e., that the skilled person would understand the claim "leave[s] room for equivalents" because the teaching "also includes the use of Purasorb" shows that the court treats the skilled person not only as a technical comparator but as the addressee of the patent's public notice function (NL - Pharmathen v. Novartis / Appeal - EPLAW, 2022).

Technical Equivalence in the Dutch Case

The technical conflict at the heart of Novartis v. Pharmathen offers a compelling foundation for examining the doctrine of equivalents, precisely because both parties had

already conceded that the method in question fell outside the literal boundaries of the patent claim, leaving the substantive contest to revolve around functional correspondence and doctrinal reach. With non-literal divergence effectively off the table as a point of contention, Novartis pressed forward by asserting that Purasorb performed in a manner functionally indistinguishable from a linear PLG, which repositioned the entire infringement analysis away from textual claim interpretation and toward whether equivalence alone could serve as a sufficient basis for liability (NL - Pharmathen v. Novartis / Appeal - EPLAW, 2022).

From the Court of Appeal's reasoning, it is possible to reconstruct a structured analytical framework through which the court approached the equivalence question in three successive stages, each building upon the preceding one. The court began by grounding its analysis in the historical and technological context surrounding the literal claim boundary. It observed that the classification of a polymer as "linear PLG" had originally been tied to the initiator used during synthesis, a convention that arose not from scientific precision but from the field's inability, at the priority date, to accurately measure branching. This historical framing was consequential because it recast the literal claim language not as a fixed definitional boundary but as a functional proxy shaped by the technological limitations of its time, thereby opening the door to treating subsequently demonstrated structural properties as germane to whether an accused polymer should be regarded as equivalent under later circumstances (NL - Pharmathen v. Novartis / Appeal - EPLAW, 2022).

The court then turned to a functional problem–solution assessment, concluding that the Pharmathen method addressed the same underlying problems that the patent was designed to solve and that Purasorb discharged the same function as the claimed linear PLG. This reasoning was notable for locating equivalence in practical correspondence and problem-solving parity rather than in nomenclature or initiator-based classification, signalling that functional overlap within context carries determinative weight independently of literal linguistic alignment (NL - Pharmathen v. Novartis / Appeal - EPLAW, 2022).

The third stage of the court's analysis introduced a temporal dimension by anchoring the skilled-person clarity assessment to the moment Pharmathen began using the contested method. At that point in time, a publication had become available that permitted branching to be determined with reasonable accuracy, and empirical data had emerged showing that Purasorb contained a substantial proportion of linear PLG. Treating this body of knowledge as the relevant informational baseline, the court concluded that the equivalence of Purasorb would have been sufficiently apparent to an ordinarily skilled person, and therefore that the method fell within the patent's protected scope. The "sufficiently clear" standard embedded in this conclusion is doctrinally significant because it articulates the threshold of competitor notice that the law requires before a variant will be treated as an infringing equivalent (NL - Pharmathen v. Novartis / Appeal - EPLAW, 2022).

Beyond the three-stage structural analysis, the court also addressed the equity and legal certainty requirements that Dutch doctrine imposes on any extension of protection beyond literal claim language. On the equity side, the court found that Pharmathen had in effect applied the patent's teaching and thereby captured the associated benefits, satisfying the fairness requirement for extending protection to the patentee. On the certainty side, the court reasoned that because the skilled person would read the claims as leaving room for equivalents and would understand the teaching to encompass the use of Purasorb, competitors were not placed

in an unfairly uncertain position. Taken together, these two pronouncements reveal the court's underlying doctrinal logic, namely that equivalence is warranted when the accused party is substantively implementing what the patent teaches while the broader competitive community retains adequate notice of that scope through the lens of the skilled person's knowledge of the public record (NL - Pharmathen v. Novartis / Appeal - EPLAW, 2022).

Cross-Border Remedies and Parent-Company Infringement

The litigation's practical significance was considerably amplified by the remedial strategy Novartis pursued throughout the proceedings. Novartis sought cross-border injunctive relief extending across all designated states in which the patent remained in force, Greece included, and this relief was granted at the preliminary injunction stage in The Hague and substantially upheld on appeal, making cross-border preliminary protection a defining feature of the case rather than an incidental procedural element.

The procedural trajectory that led to this outcome followed a recognisable pattern of forum migration. After Novartis failed to obtain preliminary relief in Greece, where the Greek court found no infringement, it redirected its litigation strategy toward the Netherlands, targeting the Dutch parent company Pharmathen Global rather than the Greek manufacturer directly. The Hague court granted broad cross-border relief on the basis that the Dutch parent exercised controlling authority over the group's other entities, which the court treated as a sufficient jurisdictional and practical foundation for extending the injunction's reach across multiple states through a single order directed at the parent (NL - Pharmathen Global v. Novartis / Supreme Court - EPLAW, 2024).

This cross-border posture generated a distinct layer of procedural controversy beyond the technical infringement dispute. Pharmathen Global contended that the Dutch court was obligated to recognise and defer to the Greek preliminary decision under Article 36 of the Brussels I Recast Regulation, and further argued under Greek law principles that one court's decision could not effectively be displaced by a later decision involving a different party, even where the practical consequence would be to override the earlier ruling. The case therefore implicated not only substantive patent doctrine but also the transnational procedural coherence of preliminary relief across European jurisdictions (NL - Pharmathen Global v. Novartis / Supreme Court - EPLAW, 2024).

A further doctrinal development of enforcement significance emerged at the appellate stage in the recharacterization of the parent company's role. The preliminary injunction judge had framed Pharmathen Global's liability in facilitation and general tort terms, treating it as having unlawfully enabled infringement committed elsewhere. The Court of Appeal departed from this framing and concluded that the parent's central and controlling activities themselves constituted direct infringement, adding that even where the manufacturing acts were not physically performed by the parent, the parent remained liable as a direct infringer by virtue of its position as the responsible controlling party. This doctrinal elevation from derivative to direct liability meaningfully strengthened the basis for injunctive relief against the parent by anchoring that relief in the parent's own conduct (NL - Pharmathen v. Novartis / Appeal - EPLAW, 2022).

Notwithstanding the breadth of the cross-border relief ultimately affirmed, the appellate proceedings also reflected judicial sensitivity to the risk of direct collision with the Greek proceedings. The Court of Appeal identified a problem with the specific command requiring

Pharmathen Global to instruct its Greek subsidiary to cease infringing activity in Greece, and the Supreme Court's subsequent summary confirmed that this portion of the judgment had been annulled. This targeted adjustment illustrated that appellate courts may preserve the overall cross-border injunctive architecture while excising particular commands that create an irreconcilable conflict with earlier foreign preliminary determinations (NL - Pharmathen Global v. Novartis / Supreme Court - EPLAW, 2024).

The Supreme Court's handling of the cassation appeal ultimately consolidated these outcomes. Rather than disturbing the appellate configuration, the Supreme Court denied the appeal without extended reasoning, leaving intact both the equivalence finding and the characterisation of the parent's directing conduct as constituting direct infringement. The practical effect was to stabilise the Court of Appeal's reasoning as an operative enforcement template, available to future litigants seeking to combine cross-border relief with an equivalence-based infringement theory through coordinated parent-level proceedings in the Netherlands (NL - Pharmathen v. Novartis / Appeal - EPLAW, 2022).

Limits and Safeguards

The sources provide one especially concrete model of a limiting safeguard: the German Formstein defence. One source explains that, in 1986, the German Federal Supreme Court "recognised that there is no infringement by equivalence if the accused embodiment is not eligible for patent protection," and another describes the Formstein defence as a limitation that "precludes the extension of claims … to encompass … embodiments that are not novel … or are obvious in light of the prior art (Pinsent Masons, 2026). This defence therefore performs a boundary-maintenance function by preventing the doctrine of equivalents from becoming a pathway to capture embodiments that could not have been claimed validly (because they fall within the prior art or are obvious) (Sonntag, 2013).

The German/UPC-style three-question structure described in the UPC-related commentary also expresses an internal constraint: it requires that the skilled person's considerations remain "focused on the essential meaning of the teaching according to the patent claim," such that the skilled person "regards the embodiment as equivalent." This "essential meaning" phrasing implies that equivalence is not meant to detach from the claim language entirely, but should remain oriented to what the patent actually teaches through the claim as interpreted by the skilled person (Pinsent Masons, 2026).

When placed alongside the Dutch Court of Appeal's legal-certainty requirement, the comparative material reveals a shared doctrinal commitment to skilled-person notice as the mechanism through which the doctrine of equivalents is prevented from expanding into an instrument of unpredictable liability. The Dutch court's formulation of this requirement was precise in its expression: the claims were understood to leave room for equivalents because the patent's teaching was readable, through the eyes of the skilled person, as extending beyond its literal language to encompass the variant in question. The certainty inquiry was therefore not directed at whether competitors had subjective awareness of the scope, but at whether that scope was objectively discernible to a person with the relevant technical knowledge engaging with the teaching as a whole (NL - Pharmathen v. Novartis / Appeal - EPLAW, 2022).

What gave this inquiry its particular texture in the Novartis proceedings was the court's explicit reliance on temporal context as a framing device. The "sufficiently clear" standard was not applied in the abstract but was anchored to a specific informational state, namely the body

of knowledge available at the moment Pharmathen began using the contested method. The emergence of a publication permitting branching to be assessed with reasonable accuracy, combined with empirical data confirming a substantial linear PLG content in Purasorb, collectively constituted what the court described as "new information" that crystallised the skilled person's ability to recognise the variant as equivalent. The certainty threshold was therefore treated as a dynamic rather than fixed criterion, responsive to shifts in the accessible technical knowledge base over time (NL - Pharmathen v. Novartis / Appeal - EPLAW, 2022).

The broader comparative significance of this approach lies in how it mediates the tension between patentee protection and competitor reliance. By conditioning the extension of scope on what the skilled person could have understood from publicly available material at the operative moment, the court preserved the functional reach of the patent without exposing competitors to liability for conduct undertaken in the absence of adequate notice. This configuration suggests that across jurisdictions engaging seriously with equivalence doctrine, the skilled person functions not merely as an interpretive reference point for claim construction but as the doctrinal anchor through which proportionality between protection and certainty is maintained (NL - Pharmathen v. Novartis / Appeal - EPLAW, 2022)..

Synthesis

Considered in its entirety, Novartis v. Pharmathen emerges from the sources as a high-consequence convergence of three mutually reinforcing enforcement elements. The case presented a structured equivalence analysis explicitly connected to the Pemetrexed line of authority, a factual configuration in which literal non-infringement was not in dispute yet infringement was nonetheless established on the ground that the substituted polymer discharged the same function and addressed the same underlying problems as the claimed element, and a cross-border injunction directed at a controlling parent company that survived appellate scrutiny and was left undisturbed when the Supreme Court summarily denied cassation. The Court of Appeal's deliberate engagement with both equitable protection and legal certainty as operative doctrinal requirements, alongside its reliance on what would have been sufficiently apparent to the skilled person at the moment of the contested conduct, illustrates that Dutch doctrine, at least as the sources report it, incorporates balancing considerations as internal features of the equivalence test rather than treating them as extrinsic policy concerns invoked only to moderate the (NL - Pharmathen v. Novartis / Appeal - EPLAW, 2022).

The comparative dimension of the analysis adds a further layer of significance by demonstrating that European equivalence frameworks become more administrable when they are structured around explicit limiting principles. The German Formstein defence exemplifies one such structural constraint, operating to prevent the doctrine from sweeping in embodiments that would themselves have been ineligible for patent protection, whether for want of novelty or on grounds of obviousness over the prior art. The essential meaning requirement, operative in both German doctrine and the emerging UPC framework, supplies a complementary internal constraint by requiring that any finding of equivalence remain genuinely anchored to what the skilled person would understand as the claim's substantive technical contribution. Within the evidentiary boundaries of the present sources, these two design choices collectively illustrate how doctrinal architecture can be calibrated to preserve the doctrine's core function of capturing functionally insubstantial variants that appropriate the benefits of the patented

teaching, while simultaneously containing the doctrine's inherent tendency toward expansive and unpredictable scope extension (Pinsent Masons, 2026).

CONCLUSION

The litigation between Novartis and Pharmathen in the Dutch courts stands as a significant illustration of how the doctrine of equivalents can function as the primary and ultimately decisive pathway to an infringement finding, even in circumstances where the parties have already accepted that the accused method does not infringe in any literal sense. The Court of Appeal's structured adoption of the four requirements for equivalence, traced through the *Pemetrexed* lineage, its determination that Purasorb performed the same function and resolved the same technical problems underlying the patent, and its separate treatment of equitable protection and legal certainty together constitute a coherent judicial methodology for extending patent protection beyond the textual boundaries of a claim, one that remains tethered to what the skilled person would recognise as within the patent's teaching at the relevant point in time. The case carries equal significance on the procedural side, where cross-border injunction practice and the strategic targeting of a controlling parent entity transformed an equivalence-based finding into an enforcement instrument of considerable geographic reach. Novartis pursued and secured injunctive relief across all designated states, obtained that relief before the Hague preliminary injunction judge, and retained it through the appellate stage despite Pharmathen Global's arguments grounded in the earlier Greek non-infringement decision. The appellate court's reclassification of the parent company's conduct from tortious facilitation to direct infringement, premised on its central and controlling role within the corporate group, deepened the enforcement architecture by treating the parent's own management conduct as the locus of liability regardless of where the physical manufacturing acts were carried out. The comparative dimension of the analysis contributes a further and practically important observation, namely that the expansive potential of equivalence doctrine is not solely a matter of doctrinal generosity but is equally shaped by the safeguards a legal system construct around it.

The German *Formstein* defence provides a prior-art-anchored external constraint that forecloses equivalence findings where the accused embodiment would itself have been unpatentable, thereby preventing the doctrine from absorbing subject matter that properly belongs to the public domain. The Dutch materials, by contrast, locate the primary constraint internally within the skilled-person inquiry, conditioning any extension of scope on what would have been sufficiently apparent from the publicly available technical knowledge at the time the contested conduct began. These represent distinct but complementary design choices, each reflecting a considered judgment about where the boundary between protected and free subject matter should be maintained. For Indonesia, these lessons underscore the importance of developing a balanced patent framework that protects pharmaceutical innovation while safeguarding public access to medicines. Future research should examine how the doctrine of equivalence might be integrated into Indonesian patent law through explicit statutory provisions or judicial interpretation, with careful attention to the safeguards necessary to prevent overreach and ensure legal certainty. Specifically, future studies could explore the potential for a *Formstein*-style defence in the Indonesian context, analyze the role of skilled-person evidence in equivalence disputes, and investigate the interaction between equivalence

doctrine and Indonesia's existing pharmaceutical patent safeguards, including compulsory licensing and bolar provisions.

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